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## When product failure is not an option









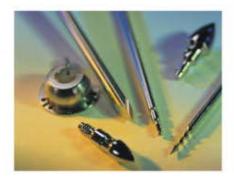


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Medical Device & Diagnostic Industry

#### Volume 29, Number 9

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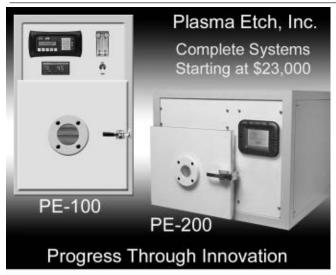
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Medical Device & Diagnostic Industry

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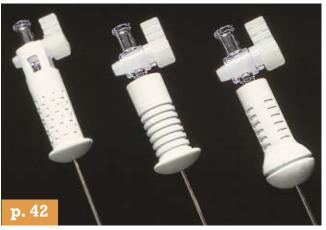


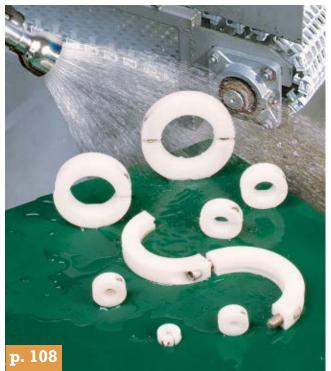




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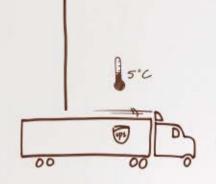
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## Congress Misdiagnoses Healthcare Spending

Some in Washington want to make further cuts to reimbursement for diagnostics, but doing so could hurt the chances for long-term savings.

It should come as no surprise that Congress is being shortsighted about something. But in this case, that "something" is reimbursement for imaging and other diagnostic tests, and a shortsighted stance could ultimately be danger-



ous. The House is proposing to cut imaging reimbursements for Medicare patients by 52%. This comes after another round of cuts came less than two years ago as part of the Deficit Reduction Act of 2005.

There is pressure on doctors and clinical laboratories to reduce the frequency of tests they order and perform, some of which can be costly.

Indeed, there is waste in the system. But the cost of failing to diagnose a condition properly is even greater. The

perspective is best summed up by this statistic: Laboratory services make up 1.7% of Medicare spending, yet affect 70–80% of medical decisions.

For example, if type 2 diabetes is properly diagnosed early on—and the test to do so costs less than \$15—the savings to the healthcare system can be as much as \$95,000, says Alan Mertz, president of the American Clinical Laboratory Association (ACLA). "That's a very powerful message," he says. "I don't know of many other things that have that kind of cost-benefit ratio."

Furthermore, CMS has said that there is no empirical evidence to show that another round of cuts is justified. What the healthcare system needs are measures that would target areas plagued by waste specifically, not massive across-the-board cuts of needed services in the name of rooting out waste.

Another sign that diagnostic costs are under siege is the competitive bidding demonstration project for clinical laboratory services. According to ACLA, it appears not to be working. Instead, ACLA says, it has disrupted services to beneficiaries in exchange for very small savings. Again, it appears to have been a case of a good idea

in theory having unintended consequences. Congress may yet fix this; Representative Nydia Velasquez (D-NY) has introduced legislation to repeal the project.

Why should the companies that make imaging and other diagnostic equipment care? Because less reimbursement or denial of access to diagnostic services means fewer tests performed. And ultimately fewer tests performed means less demand for new equipment, and fewer orders placed.

For several years AdvaMed has lobbied for changes in the reimbursement structure for diagnostic tests, which it says is outdated and provides a disincentive to innovate in the field. In 2005, the Lewin Group produced a white paper for AdvaMed that made the case for the value of diagnostics. (That paper can be viewed in the "Resources" section of AdvaMed's Web site, www.advamed.org.) Last winter, officials from AdvaMed and ACLA met to talk about why the diagnostics field is under siege and whether they should collaborate on lobbying to counteract it.

A few months ago, ACLA set up a nonprofit organization, Results for Life, to promote the benefits of diagnostic testing. The device industry should pay attention and perhaps join forces with the clinical lab industry on relevant issues.

"If reimbursement issues affect us, it will affect [diagnostic equipment manufacturers], because we are their end product," says Marc Grodman, MD, CEO of Bio-Reference Laboratories Inc. (Elmwood Park, NJ) and a member of ACLA's board of directors. "We would like to have the equipment makers with us, because what we do goes hand in hand with what they do."

AdvaMed has shown some leadership on this issue, but it is time for the device industry to take the message to another level. And the more allies the device industry can join forces with, the more likely the message is to be heard.

Erik Swain for the Editors mddi@cancom.com



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Tor Alden is the author of this month's Product Development Insight column, "User-Centered Design and the Medical Device Start-Up," beginning on page 42. Alden is principal



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64. Mackin is a project manager at Microtest Laboratories (Agawam, MA). In his previous roles at Microtest, he has helped medical device manufacturers develop cleanroom validation,

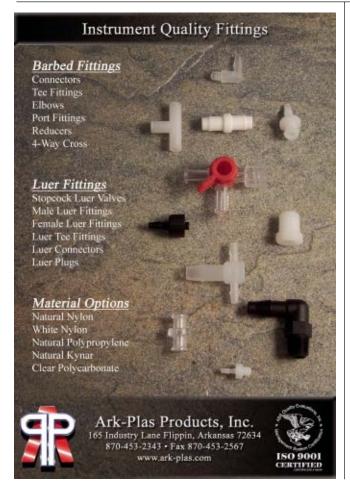
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Mackin

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Cactus Bud

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#### Report Calls for FDA Nanotech Guidance

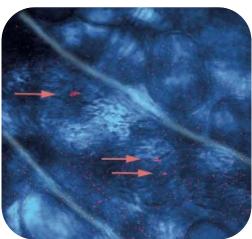
n FDA task force on nano-Atechnology recommends that the agency issue guidance on what information about nanomaterials it needs to see from medical device firms and others seeking product approvals. It does not identify a need for any new laws or regulations at this time. However, it does suggest that devices with nanoscale materials may be subjected to a higher level of scrutiny.

For products such as devices that are already subject to premarket approval, FDA has the authority to obtain information about their use of nanotechnology, the task force states in its report, which was issued in July.

Importantly, the task force endorses comments from industry and some academics that blanket restrictive policies are not the best idea, because uses

of nanotechnology are so diverse. "The evolving state of the science regarding nanotechnology may warrant a caseby-case approach to

assess whether sufficient evidence exists to show that products satisfy the applicable statutory and regulatory standards," the report states. The task force, however, does want additional



Gold nanorods will be one of many nanotechnologies that FDA will encounter.

public input on how nanotechnology should be regulated for combination products.

It would like guidance to be issued on the following subjects:

- When the use of nanomaterials may require the submission of more data.
- When the use of nanomaterials may change a product's regulatory status or pathway.
- When additional steps must be taken to address potential safety or quality issues.
- When a Class I or Class II device needs premarket approval because See Nanotech Guidance, page 22

#### **Groups Petition FDA** to Require DEHP Labeling on Devices

number of healthcare groups are Aurging FDA to mandate the labeling of polyvinyl chloride (PVC) devices that contain di-2-ethylhexyl phthalate (DEHP). In a petition and letter sent to FDA in late July, Health Care Without Harm called for the labeling of these devices due to the risk that the toxic chemical poses to young males. The organization is a nonprofit coalition that aims to reduce pollution in the healthcare industry.

The petition recommends that devices containing DEHP include a "prominent, clearly worded warning label" stating exposure risks. The label should also identify the populations that would benefit from the use of alternative devices, including pregnant or breast-feeding women and male infants. These groups could experience adverse health effects if exposed to DEHP, according to the National Toxicology Program (NTP).

Last year, a report issued by the NTP concluded that devices with DEHP can potentially interfere with the development of the male reproductive tract. The chemical, a plasticizer, is added to PVC-containing devices to make them softer and more flexible. Many types of devices, including tubing, catheters, and intravenous bags, contain DEHP. The problem is that it can leach out of a device and into the solution that comes in contact with the plastic.

According to Health Care Without Harm, the "lack of labeling allows confusion and misleading statements when companies defend the safety of their DEHP-containing devices." The group also says manufacturers confuse be healthcare providers by asserting the safety of these devices.

"Irrespective of whether or not man-ufacturers are receptive [to the proposed labeling requirement], the point is that consumers, practitioners, and purchasing agents need to know §

See **DEHP** Labeling, page 23 \( \frac{1}{6} \)

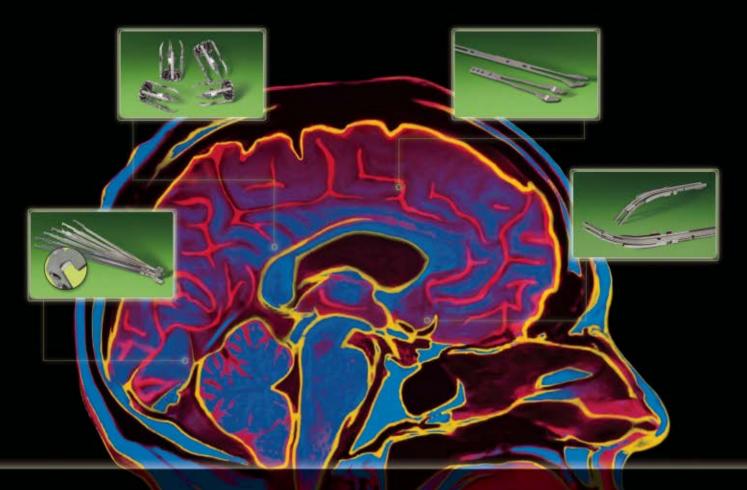
### Other**Stories**

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#### Nanotech Guidance

Continued from page 20

of the use of nanoscale materials. "A PMA might be required for a product otherwise... considered Class I or Class II if the inclusion of nanoscale material raises questions of safety or effectiveness warranting clinical studies," the report states.

- When a sponsor should submit a new 510(k) for a modification to a previously cleared device that incorporates the use or increased use of nanoscale materials.
- When industry should seek input from FDA on "significant risk" decisions regarding investigational devices that will contain nanoscale materials.

The report also suggests that any Class I and Class II devices exempt from submitting a new 510(k) after modifications are made may have to lose that exemption if they incorpo-

rate nanotechnology. This would be the case if "use of a nanoscale material were to qualify as a use of a different fundamental scientific technology." In addition, information on particle size should be required in all nanotech-related submissions, the task force says.

In the meantime, the task force encourages any firm using nanotechnology in a product being developed to communicate with the agency early on. This is especially encouraged for those using nanotechnology in combination products.

The report also does not advise adopting a single definition of *nanotechnology*, as the term is used differently among various disciplines. This may change as FDA learns more about how nanoscale materials interact with biological systems.

It does acknowledge that "a material's properties can change when size is increased or decreased into, or varied within, the nanoscale range," and so extensive testing of nanomaterials may

be necessary. By the same token, the report notes that FDA may need to add reviewers with specific expertise in nanotechnology. Also, it states, it will be important to include developments with nanotechnology as part of ongoing training for FDA personnel.

Industry needs to do its part to advance knowledge, too. "A greater understanding of the properties of nanoscale materials and of trends in material development and uses would help focus data and testing requirements," the report states.

Crucially, FDA will need to evaluate the adequacy of current testing approaches to assess the safety, effectiveness, and quality of products that use nanoscale materials. Consumer groups have expressed concern over whether current tests can predict potential longrange problems.

The task force is not recommending that use of nanomaterials be included on all labeling. It suggests that issue be considered on a case-by-case basis.

-Erik Swain



#### **DEHP** Labeling

Continued from page 20

whether or not [a] device contains DEHP so that they can make an informed purchasing decision," says Ted Schettler, MD, science director at the Science and Environmental Health Network (Ann Arbor, MI). "That's what the problem has been all along. When practitioners in hospitals are trying to address this issue, they frequently don't know if the device they're using has DEHP in it."

In 2002, FDA called attention to the issue by releasing a public health notification. It advised limiting use of DEHP-containing devices in high-risk

"[Practitioners] frequently don't know if the device they're using has DEHP in it."—Ted Schettler, MD, Science and Environmental Health Network

patients. The agency also suggested alternative materials such as silicone. And it listed a source where hospitals could find alternative devices. However, it didn't impose any labeling requirement on manufacturers.

Schettler says that more data have emerged since that notification. The new information has changed the landscape and should prompt the agency to review and consider the petition's recommendations, he adds.

"Things are sufficiently different now and it's hard to imagine an argument that [DEHP-containing devices should not] require labeling," says Schettler. "You have devices that demonstrably contain a reproductive toxicant that leaches out and exposes patients at risk to significant-enough doses to exceed FDA's tolerable exposure index."

The NTP is part of the Department of Health and Human Services. Its full report on the risks that DEHP poses to human reproduction is available online at http://cerhr.niehs.nih.gov/chemicals/dehp/DEHP-Monograph.pdf.

—Maria Fontanazza

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#### July Was Merger Month for Device **Industry**

Tt used to be that multi-billion-dollar deals in the device industry were rare. But now, they happen all the time. July was a particularly active month.

Why the increased activity? Some on Wall Street believe that the Boston

Scientific-Guidant deal convinced the industry that almost no company is too big to be acquired. That's something that employees at device firms need to remember.

Just in July:

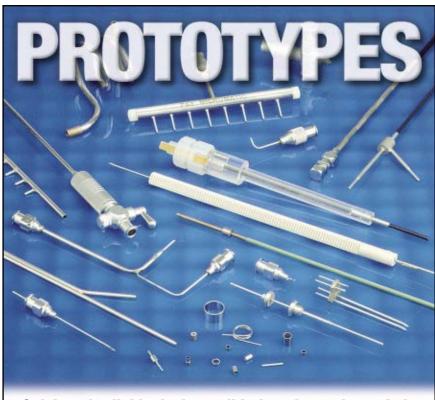
> In a move that would unite two players from opposite ends of the diagnostics sector, Siemens agreed to purchase Dade Behring for \$7

billion. Siemens is known for high-tech imaging, Dade Behring for clinical laboratory testing equipment. Siemens said its goal is to become the global leader in full-service diagnostics. Shareholders apparently thought the price was too high, since Siemens shares dropped in value after the Dade Behring acquisition was announced.

- > Medtronic announced it would buy Kyphon Inc. (Sunnyvale, CA), a firm that develops minimally invasive spine treatments, for \$3.9 billion. The deal will allow Medtronic to expand its portfolio with products geared toward older patients. Interestingly, Medtronic has an intellectual-property lawsuit pending against Kyphon. That lawsuit will be dropped upon completion of the acquisition.
- > Multi-industry conglomerate Teleflex Inc. (Limerick, PA) said it would buy Arrow International Ltd. (Reading, PA) for \$2 billion. Arrow makes catheter-based devices for cardiac and critical care. Teleflex owns a variety of device interests and has gone on a huge acquisition binge in 2007.
- > EV3 Inc. (Plymouth, MA) and FoxHollow Technologies (Redwood City, CA) announced a \$780 million merger. Both make endovascular devices, and both have won praise on Wall Street for their innovation and strong operations. Not surprisingly, shares of both firms soared after the deal was made public. The company's combined product portfolio will include atherectomy and thrombectomy devices, PTA balloons, stents, embolic protection devices, infusion catheters and wires, embolic coils and liquid embolics.

July did bring one unconsummated merger as well. GE Healthcare, after doing due diligence, announced that it was calling off its purchase of Abbott's diagnostics business, for which it would have spent \$8 billion.

--ES



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#### Software Systems Breaking Boundaries for Device Makers

Software for medical device operations tends to be divided into well-established, compartmentalized categories. But some firms recently have been trying to break the mold by introducing systems that stretch across two or more of these categories.

If this trend continues, medical device manufacturers eventually won't need as many software systems as they do now. They might even be able to access data across systems that currently can't communicate very well (if at all).

For example, Omnify Software (Andover, MA) has traditionally stuck to

based platform, device companies can also integrate it with the systems used by their contract manufacturers, contract designers, and other partners, Cimalor says.

"Extending the capability of the system to capture manufacturing, quality, and customer information, and tie it back to the product record, improves visibility to all aspects of product data. [That helps] drive better design and streamline product development even further," he adds.

Also cutting across software sectors, manufacturing execution system (MES) vendor Camstar Systems Inc. (Charlotte, NC) and PLM vendor PTC Corp. (Needham, PA) have teamed up. They now offer software that combines features from both types of systems.

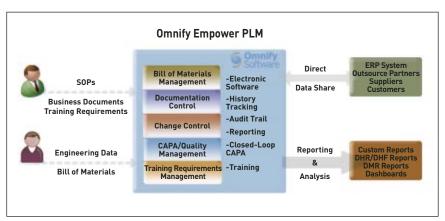


Figure 1. PLM software now offers modules that ensure compliance with the QSR.

product life cycle management (PLM) systems. But now it has come out with PLM software that has modules that ensure compliance with the quality system regulation. For example, it has a quality management module that automates the capture and routing of data related to product issues and defects in a closed-loop corrective and preventive action system. That previously required a separate software system. Other modules include a training monitor and an automated project management system.

"Before, to do all these things, there was no unified system," says Chuck Cimalor, Omnify's chief technical officer. "You had to export things from one system into another. But now, all modules are already integrated. You can see all quality issues at once, all customer issues at once, and so on."

Because the system is on a Web-

The idea, the firms say, is to synchronize product and process management.

The system can, among other things, integrate the software used for design and the software used for manufacturing, says Chris Parsons, Camstar's director of marketing. "It gives [design engineers] a full feedback loop [from manufacturing], and they can exchange data in real time," he says. "This capability gives everyone the knowledge base needed in order to execute design for manufacturability."

A white paper written for Camstar and PTC by Daniel Matlis, founder and president of healthcare analysis firm Axendia (Yardley, PA), sheds more light on the boundaries the system wants to break.

Complying with FDA regulations, he wrote, comes down to answering three questions: What do you make, how do you plan to make it, and can you prove it? Information to answer the first



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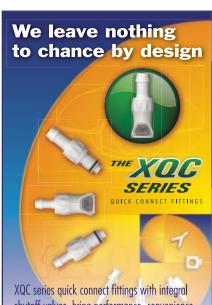
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#### **NewsTrends**

question is in the design history file (DHF). Information to answer the second question is found in the device master record (DMR). And the solution to the third question is found in the device history record (DHR).

The problem, he wrote, is that for most device manufacturers, the answers are found in separate standalone systems (and sometimes on paper). The DHF resides in computeraided design and product development systems. The DMR resides in document management, product development, and manufacturing specification systems. And the DHR resides in various MES files. These include lot and batch records, equipment maintenance and calibration records, and operator certifications.

"For medical device manufacturers, this requirement necessitates a direct link and constant feedback between the DMR, DHR, and DHF," Matlis wrote. "To achieve this goal, device manufacturers must close the loop between the PLM and MES systems. However, the level of synergy required to meet the challenges . . . can only be achieved through the use of a fully integrated product development, manufacturing, and quality platform. This

integrated platform approach can improve performance of business processes and facilitate robust design, operational excellence, regulatory compliance, quality systems management, change management, and requirements management."

Achieving that, he concluded, should allow device manufacturers to support continuous improvement. —*ES* 

#### AAMI Board Gains Three Medtech Experts

Three experts in medical technology have been elected to the board of directors of the Association for the Advancement of Medical Instrumentation (AAMI; Arlington, VA).



Francoeur serves on AAMI's Technology Management Council.

David Francoeur is vice president of operations at TriMedx (Indi-

anapolis), a provider of clinical engineering services. He has more than 24 years of experience in the areas of

## Law Partner Brings PMA, Compliance Experience to MD&DI

Jeffrey K. Shapiro has joined MD&DI's Editorial Advisory Board. Shapiro is a director at the law firm Hyman, Phelps, and McNa-

mara. From 2000 to 2007, he was a partner with the firm Hogan & Hartson. Before that, Shapiro served in the office of legal counsel at the Department of Justice.

As a member of the Editorial Advisory Board, Shapiro adds considerable expertise to the magazine. His focus is primarily on assisting medical device and diagnostics manufacturers in complying with regulatory requirements such as obtaining premarket clearance, handling

adverse-event reporting, maintaining quality systems, and responding to FDA-483s or warning letters. His expertise is on the legal aspects of mergers and acquisitions, combi-

nation products, and human and cellular tissue products.

A long-time contributing editor to MD&DI,



Shapiro brings expertise in premarket approvals and FDA compliance.

Shapiro is also a coeditor of Promotion of Biomedical Products, a textbook on FDA regulations on promoting and advertising medical devices published by FDLI in 2007. He is also coauthor of "Combination Products: How to Develop the Optimal Strategic Path for Approval" for the Web site www.fdanews.com. He has written numerous articles in the Food and Drug Law Journal, Regulatory Affairs Focus, and FDLI Update.

Shapiro has a JD from Harvard Law School (1986), and he holds a BA from Brown University. He is a member of the Federalist Society.

environmental services, plant operations, and clinical engineering. Since 2004, he has served on the Executive Committee of AAMI's Technology Management Council. Francoeur also serves

on the editorial board of AAMI's journal, Biomedical Instrumentation & Technology.

Joel R. Gorski, PhD, is director of business development for NAMSA (Northwood, OH), which evaluates medical devices tometer working and materials for group. safety and efficacy.



Gorski is cochair of AAMI's resis-

He is active on numerous AAMI working groups. He has been cochair of the AAMI chemical indicators working group (AAMI/ST/WG 06) since 1996 and cochair of AAMI's working group on resistometers (AAMI/ST/WD 91) since 1999. Gorski is also a member

of MD&DI's editorial board.

Leighton Hansel is director of regulatory affairs for the medical group at Abbott (Abbott Park, IL). Prior to joining Abbott, he served at FDA, including 13 years as a division director in CDRH. He has been involved in



Hansel, who served 13 years at CDRH, has worked with AAMI for 10 years.

standards work at AAMI for the past 10 years. His goal is to convince more executives to support standards efforts.

"AAMI's place at the forefront of the medical device field is in many ways directly attributable to the talents and dedication of the individuals who have served on its board of directors over the last 40 years," said AAMI President Michael J. Miller. "With Leighton, Joel, and Dave, who have already made significant contributions to AAMI and to the industry, AAMI's future is in very capable hands. Their talents and insights will be key assets in facing the challenges that lie ahead for the association and for the field."—*ES* ■



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## **R&D Digest**

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## Medical Imaging: The Brain Is Ready for Its Close-Up

Researchers at the University of California, Irvine, (UCI) may have a leg up, especially when it comes to visualizing the brain. The university has a HIPerWall system that enables high-definition rendering of images, to the point at which individual brain cells (or cells of other organs) can be seen.

Such a high level of visualization could help scientists understand brain diseases such as schizophrenia and Alzheimer's disease. "These diseases cause lesions, plaques, and other very small changes in the brain. In order to understand [them], we must look at the cellular level," said Joerg Meyer during the ASME Frontiers in Biomedical Devices conference in June.

Meyer is an assistant professor in the electrical and computer engineering department at the university. "Our goal is to improve the quality of medical images and make the images representative of the actual body part," he said.

The HIPerWall is an array of 50 flatpanel tiles that has the capacity to display more than 200 million pixels. Images at the cellular level can take up to 76 GB of space (enough to fill up one PC hard drive). Meyer said the greatest challenge they face is finding storage for the more than 1400 images the team has collected.

The system works by combining histological images, which are stacked to produce high-resolution renderings, and noninvasive methods such as computed tomography (CT) or magnetic resonance imaging, which is known for high alignment.

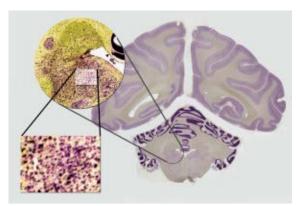
Researchers developed a visualization engine that produces three-dimensional (3-D) images from stacks of 2-D cross sections. In addition to the high-resolution images, annotated atlases can also be displayed at the same time, enabling simultaneous views of macro and microscopic structures from the same



At the University of California, Irvine, researchers can use a 200 million-pixel display system to develop medical imaging techniques for diagnostics.

imaging set.

To demonstrate, Meyer presented high-resolution images of a rhesus monkey brain, which is about the size of a walnut. "We froze the brain and then cut it into 1400 very thin slices. Then we put the sections into a film scanner, which produced high-resolution digital images. The image quality is about 10 times better than with a typical 2-megapixel digital

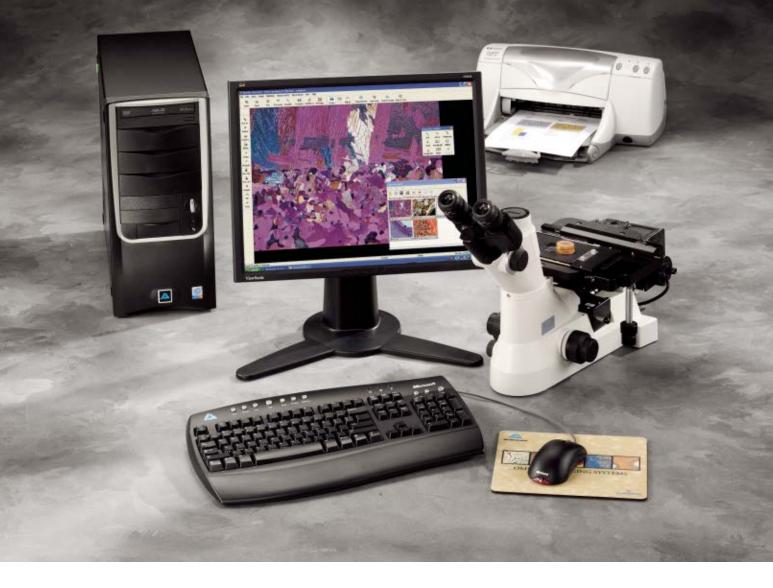


Rendering combined with CT imaging enables visualization down to the cellular level, as demonstrated with this cross section of a monkey brain.

## Other **Stories**

Flowmeter Could Diagnose Breathing Disorders, p. 30 >>

Brain Chip to Control Seizures, Artificial Limbs, p. 32 >>



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Buehler Ltd • 41 Waukegan Road Lake Bluff, Illinois 60044 • USA Tel: (847) 295-6500 • Fax: (847) 295-7979 Email: info@buehler.com Web Site: http://www.buehler.com camera," he said. The scanning was done at the Center for Neuroscience at the University of California, Davis. UCI processed the images, aligned them, and recombined them into a three-dimensional atlas of the monkey brain.

Meyer explains that there is one-toone mapping between the functional regions and circuits of a monkey brain and a human brain. "We hope that our 3-D brain atlas will replace 2-D drawings in textbooks, because it is more intuitive and more instructive. It allows us to compute a virtual flight through the brain. We can zoom in and out, and we can navigate to every region of the brain and look at the cellular structure."

Besides brain imaging, the researchers are also working on a computational heart-imaging model that has 22 million segments, rendered in

real time. They are also looking at stem cells to map for differentiation.

And the team is also exploring ways to acquire images that do not rely on invasive histology. The engineers are working with a system called optical coherence tomography (OCT), which

"Image quality is about 10 times better than with a typical 2-megapixel digital camera."

—Joerg Meyer, University of California, Irvine

uses lasers to scan very thin layers of tissue, very close to the cellular level. "It is near the results we get from histology, which is the standard," Meyer explained.

The National Institute of Mental Health funded the Monkey Brain Atlas project. The HIPerWall project was funded through a grant from the National Science Foundation.

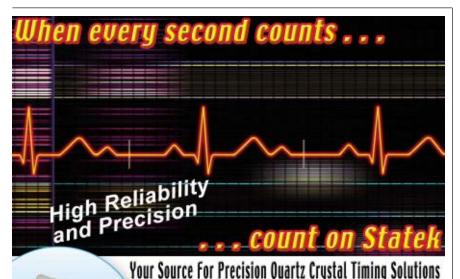
—Heather Thompson

#### Flowmeter Could Diagnose Breathing Disorders

Researchers have designed a disposable flowmeter to detect sleep-related breathing disorders, such as snoring and sleep apnea. The device could also be used to identify breathing problems in patients with chronic obstructive pulmonary disease and other lung ailments. And it could improve the detection of sleep disorders in children.

The compact pneumotachograph measures ventilation during sleep or when in a sleep-like state. It can provide measurements in infants and others with smaller airways, and assess airflow in each nostril. Because the flowmeter is disposable, infections won't be transmitted between patients.

The concept for the flowmeter originated during the severe acute respiratory syndrome (SARS) epidemic in China. It was developed to monitor patients in general wards and



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32 kHz - 160 kHz 14 MHz - 250 MHz

Approx.

Actual Size

Side View

**CX11** 

100 kHz - 180 kHz

20 MHz - 50 MHz

intensive-care units in hospitals.

According to device inventor Hartmut Schneider, MD, PhD, the high accuracy of the airflow meter will help doctors find disorders in situations where they previously went undetected. Schneider is an assistant professor at The Johns Hopkins University School of Medicine.

"The current standard in diagnosing breathing disorders during sleep is based on technologies from the late 1990s and, more importantly, it's based on the classification of recordings from the obese male population," says Schneider. Doctors are now seeing many more women and children who have sleep-related breathing disorders. But the criteria aren't well defined. "An accurate measurement of airflow and ventilation would help us to detect a breathing disorder and define it with a higher accuracy."

The current prototype consists of a recording unit and a disposable measurement unit. When a patient exhales, the air is expired to the disposable unit,

which can be configured to be mounted in-line with ventilator tubes or masks. The recording unit has microelectromechanical pressure transducers that provide a sensitive and stable flow signal. The unit then calculates the difference between total and static

The concept for the flowmeter originated during the SARS epidemic in China.

pressures to determine the air velocity and flow rate.

Schneider thinks the flowmeter will evolve in the same way that diabetes glucose measurement devices have changed over time. He envisions its use by both patients in the home and clinicians in hospitals.

The finished device may be a small mask about the size of a clown's nose, and the electronic module may be as

small as a USB key. The sensor and recording unit could be placed in the mask with thin wire connecting it to an external electrical power source. Production costs are anticipated to be low, so manufacturing a disposable device should be feasible.

The team is working to improve flow measurement accuracy and the signal-to-noise ratio. It also plans on developing an electronics module that attaches directly to the flow sensor. It's also possible that the device could have a wireless interface.

Other potential changes to the flowmeter include implementing a pulse oximeter that can be mounted on the nose or forehead to monitor oxygenation. The researchers are exploring the use of onboard software algorithms that measure upper-airway obstruction from a continuous airflow signal recorded during sleep.

Key Technologies Inc. (Baltimore), a development company, is a coinventor of the device.

-Maria Fontanazza



#### Brain Chip to Control Seizures, Artificial Limbs

With the ability to process brain signals and stimulate neurons, a neuroprosthetic chip could have the power to prevent seizures and control artificial limbs. Researchers at the University of Florida (UF; Gainesville) have the components needed to create the brain chip. Now they must successfully integrate the technologies into one package.

Initial applications of the device focus on treating paralysis and epilepsy. The chip will be able to sense a problem or intent from a person's brain, decode the signal, and then process it to deliver therapy through the device's interface.

"The brain chip is a means to bypass damaged tissue in the nervous system," says Justin Sanchez, PhD, assistant professor of pediatric neurology, neuroscience, and biomedical engineering at UF. "We can use engineering principles to help resolve some of the functional deficits that may be in the nervous system."

The researchers have already developed an algorithm and tested new types of electrodes. These will interface with the brain to provide signal sensing. Data that are recorded on the chip can be downloaded wirelessly, recorded onto a separate system,

and then reviewed by the user at a later time.

"We've developed a new signal representation that enables the fully implantable device to send out many channels of neuronal modulation synchronously and wirelessly," says Sanchez. "We have a pulse-based representation of neuronal firing that we can use to overcome some of the power and bandwidth issues." The researchers also developed new signal and coating techniques to obtain more data from the implant.

The chip will be about 10–12 mm in diameter and 1–2 mm thick. It will be implanted between the top of the skull and the bottom of the scalp.

The main design challenge will be to combine the electrodes, amplification, signal-processing, and wireless technologies into a small, portable device that is rechargeable or can run on a primary battery for a long period of time. The researchers also face power constraints associated with wireless data transmission and sending multiple channels of data in real time.

To use the brain chip to treat paralysis or epilepsy, the device must be able to decode and process the neural representation to deliver therapy. To do this, the researchers must improve the



Justin Sanchez from the University of Florida says the chip could bypass damaged cells in the nervous system.

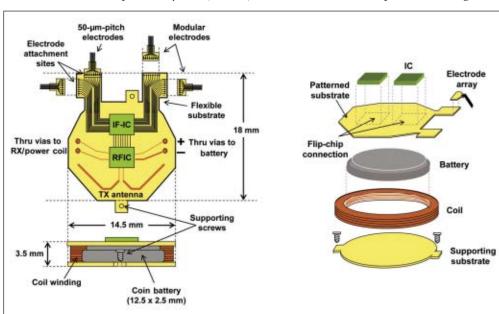
device's signal analysis. This will help the implant determine a patient's intent to move a prosthetic limb or control a wheelchair, for example. When attempting to prevent epileptic seizures, the device must identify abnormally firing neurons in a reasonable time frame to be able to disrupt the irregular neural activity.

The National Institutes of Health gave the researchers a \$2.5 million grant for their work. Sanchez is working closely with colleagues at UF's

College of Engineering on the project. Jose Principe is involved in the signalprocessing aspect; John Harris is handling analog circuit design; Rizwan Bashirullah is responsible for the wireless system; and Toshikazu Nishida is involved with the microelectromechanical system and the fabrication of new electrodes.

The next step for them is to incorporate the individual technologies into a complete system, test the components together in vivo, and show proof of concept. A prototype could be ready for human testing within a few years.

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A portable wireless system records neuronal modulation data downloaded from the implantable brain chip. Graphic reprinted with permission from IEEE, 2007.

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## FDA House Judge Rules against TMJ Implants

The device firm was given 30 days to file full financial disclosures before hefty civil money penalties would be imposed.

#### James G. Dickinson

MJ Implants (TMJI; Golden, CO) has lost the latest round of its battle against CDRH. In July, FDA administrative law judge Daniel J. Davidson ruled in favor of CDRH on every count.

In a sweeping 12-page initial decision, Davidson upheld all aspects of CDRH's case for \$630,000 in civil money penalties against the manufacturer of jaw implants. TMJI has not filed 17 medical device reports (MDRs) since 2004 and has tried in vain to obtain FDA's medical or scientific rationale for demanding them.

Davidson gave TMJI 30 days to file full financial disclosures prior to imposition of the civil money penalties. The fines could take effect as early as September. The company has said payment could compel it to shut down. It is considering an appeal to federal court and to Congress. There, members might have sympathy for its position, based on a June 25 Wall Street Journal editorial titled "FDA's Mean Devices."



That piece accuses FDA of bullying small device companies that don't have the resources to absorb market losses caused by agency demands.

Administrative law judges are empowered only to make "recommendations"—not judicial decisions—in disputes between their host agencies and aggrieved parties. Recourse from their "recommendations" is legally available through administrative appeals and U.S. district courts.

TMJI attorney Lynn Watwood wrote a scathing critique of Davidson's decision. Watwood said the decision showed "clear animus" toward the company, ignored documented evidence, and "pulled facts and statements out of context." He also said the decision "ignored the clear language of the MDR regulation that requires . . . application of the 'reasonableness' test."

Watwood said Davidson did not adequately consider a pivotal issue in TMJI's case. When TMJI disagreed with CDRH's decision to mandate the filing of 17 MDRs, it appealed to the FDA commissioner. The company contends that the issue was not substantively reviewed by the commissioner and should have been resolved on its scientific merits by him before the penalties were asserted.

Davidson, however, writes: "After reviewing TMJI's appeal request, FDA denied the request. In July 2005, FDA Commissioner for External Affairs Sheila Walcoff notified TMJI in writing that its appeal request was denied and that the agency planned to file this action." In a small-print footnote, he adds: "The wording '... that the agency planned to file ...' this action is somewhat inaccurate because it appears that this communication was actually sent after the [civil money penalties complaint] was filed."

He then goes on to characterize TMJI's protests as the company "apparently seeking further reconsideration of [its] position from the commissioner." But the firm says it never received any consideration in the first place. Walcoff's letter said any consideration of the appeal would be duplicative and not efficient owing to the

## Other **Stories**

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#### Wrap-Up

civil money penalties case.

Davidson's decision then notes that he had twice rejected TMJI requests to stay the civil money penalty proceedings pending further consideration by the commissioner of the company's position. Why? "Because it appeared highly unlikely, considering the history of this matter, that any further consideration by [the commissioner] would result in a decision contrary to those previously rendered."

On this point, Davidson concludes that TMJI's interpretation of the MDR regulation "has been considered and rejected by FDA on more than one occasion. The fact that the administrative process provides additional avenues for seeking reconsideration of rulings does not justify the delay of a formal evidentiary proceeding. Under the circumstances, the [civil money penalties action] was not filed prematurely and respondents have had (and continue to have) ample opportunities to have their interpretation of the MDR regulation considered." This

conclusion is without foundation, Watwood said.

He argued that TMJI's position has never been considered by FDA. That would mean its appeal was never denied, but instead rejected without review. "CDRH is not 'the FDA,' just a lower branch of FDA, with admittedly no final authority to resolve appeal requests to the commissioner," Watson said. FDA simply said that the law does not require the commissioner to accept all petitions for review. Another disagreement stemmed from the definitions of serious injury and permanent injury. both of which necessitate filing an MDR. Watwood said Davidson ignored testimony given in April by medical experts who could not agree on what is considered a permanent nontrivial injury and the definition of the phrase cause or contributed to. In fact, he said FDA's own witnesses, none of whom had experience with TMJI's devices, "agreed that 'reasonable men' (physicians) may

differ in applying this definition to an adverse medical event."

"That is why in the opinion of respondents, the term *reasonable* in conjunction with the medical judgment of a company's expert appears in the MDR regulation as a justifiable reason for filing or not filing an MDR. Thus, the standard is the 'reasonableness' of the company's decision."

Davidson, he said, rejected this interpretation, applying instead an "absolute" standard favored by FDA "which does not appear in the MDR regulation. This finding moots FDA's MDR regulation requiring a company under threat of sanctions for noncompliance to investigate adverse events to reach a 'reasonable' determination. If, as FDA argues under the stricter standard, there is a previously implanted device 'intrinsically' present, a company can never rule out that its device caused or contributed to the injury. Thus an investigation required by the MDR regulation is utterly meaningless."





Maybe in the end, no one wins. That's the assessment of a device industry attorney who anonymously posted the following on my Web site:

TMJI has chosen to fight to the death over its duty to report to FDA on 17 cases that the FDA already knew about from Med-Watch forms initially filed to the agency and forwarded to TMJI. TMJI has had an option, since day one, of filing MDRs with disclaimers such as 'unable to confirm it is our product,' 'unable to verify information with a health professional,' and 'appears to be related to a preexisting condition unrelated to the device.' TMII chose not to follow that course. (Of course, each disclaimer carries with it the implied representation that TMJI is not lying to the government. Could that be a factor?) As a result, the taxpayers and TMJI have spent large sums of money disputing the regulation. Has TMJI benefited from its refusal to file MDRs with appropriate and truthful disclaimers? Has FDA benefited from a battle that could have been circumvented by clarifying its regulation through noticeand-comment procedures? Has anyone benefited from this dispute?

#### Bausch & Lomb Lens Solution Plant OK'd

An FDA inspection of a troubled Bausch & Lomb contact lens solution manufacturing plant and distribution center in Greenville, SC, found that both facilities are in compliance, the company said in July. The inspection came months after the firm received a warning letter detailing quality system problems at the plant.

Bausch & Lomb said that at the end of the most recent inspection, FDA indicated that all corrective actions required from the earlier inspection and subsequent warning letter had been completed. No negative observations were made.

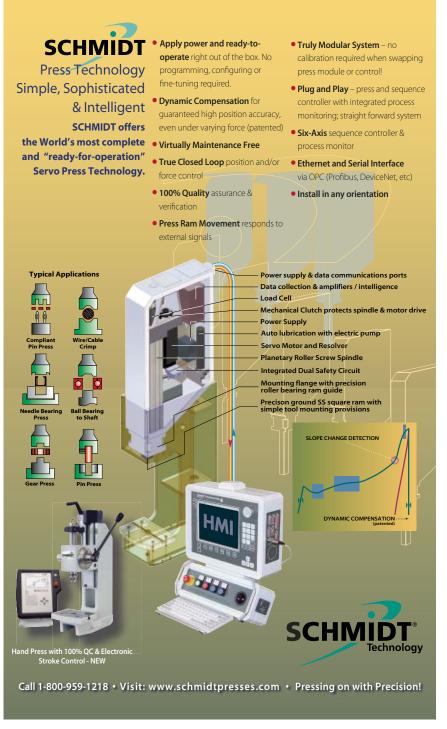
A seven-week FDA inspection at the facility that began in March 2006 found "serious systemic" quality system regulation (QSR) problems, according to the warning letter issued in October from FDA's Atlanta district office. It acknowledged the company's

efforts to address outstanding deficiencies but said the QSR violations were systemic and relevant to all products manufactured at the facility.

The warning letter also said the firm's contact lens solutions were misbranded because the company failed or refused to furnish information required by the medical device reporting regulation. Atlanta district director Mary Woleske said the company's

responses to violations noted on the FDA-483 were inadequate, and that it often failed to provide necessary documentation of corrective actions taken.

The March 2006 inspection concentrated on the company's MoistureLoc contact lens solution, which was subject to a worldwide recall to eliminate health risks associated with *Fusarium keratitis*. The warning letter said FDA's



#### Wrap-Up

investigator did not find problems that would warrant product recall or field correction with other products produced at the facility.

## Shelhigh Throws in the Towel

In a June 22 federal court consent decree, Shelhigh Inc. (Union, NJ) agreed to stop distributing its implantable medical devices until it complies with CGMPs, the quality system regulation, and medical device reporting requirements. The company's decision came after nine weeks of defiance.

At the height of its defiance, Shelhigh publicly accused FDA of refusing to disclose MDRs implicating the company's devices in public health concerns. Instead, the company charged, FDA invited it to submit a Freedom of Information Act request while the agency alerted healthcare providers and patients to file such reports.

The consent decree requires Shelhigh to retain independent expert consultants to inspect its facility and certify to FDA that corrections have been made. FDA also will continue to monitor the firm's progress through a series of periodic inspections.

"Shelhigh may resume manufacturing, but not distributing, devices in phases after FDA has approved its plan for bringing its seized products and manufacturing processes into compliance with FDA law," an FDA news release stated.

"After Shelhigh has completed corrective actions and been allowed to resume manufacturing, the company must hire an independent auditor to inspect its facility at least once a year. Results of these audit inspections will be reported directly to FDA," the release continued. If the company fails to comply with the decree, FDA can order additional sanctions, including recalls and monetary penalties.

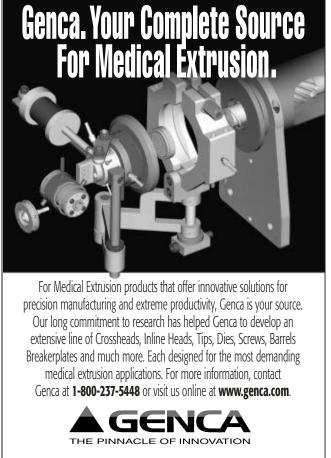
"It is critical that companies comply with FDA's manufacturing rules so that

medical devices, especially the kind of implantable devices made by Shelhigh, are safe and effective," CDRH Director Daniel Schultz said in the release.

On April 17, U.S. marshals acting on a request from FDA seized all finished devices and components at Shelhigh's manufacturing facility because of concerns about the devices' sterility. The firm makes a variety of devices, including pediatric heart valves and conduits, surgical patches, dural patches, annuloplasty rings, and arterial grafts.

After the seizure, FDA requested that Shelhigh recall all of its medical devices remaining in the marketplace. The company refused. In what may be seen as a small victory for the firm, however, FDA did not invoke its authority to require Shelhigh to recall its devices. However, in May, Integra LifeSciences Corp. (Plainsboro, NJ) said it was recalling all of Shelhigh's EnDura No-React Dural Substitute products, which Integra distributes.





# Judge Skewers FDA Preemption in Device Case

Former FDA chief counsel Daniel Troy was known for his controversial efforts while in office to promote across-the-board FDA preemption of state tort cases. That is, he sought to prevent law-suits from being filed in state courts over safety issues already decided by FDA. A federal judge in a recent device case disagreed, and the decision could deal a blow to Troy's view.

In Leopoldo Duron v. Guidant et al., Minnesota federal judge Donovan W. Frank effectively revived the idea that state torts complement and strengthen resource-depleted FDA's regulatory oversight of industry. While in office and since, Troy has argued the opposite, saying that it deterred companies from sharing all they knew with the agency for fear of attracting tort litigation, and acted as a brake

on innovation. Several judges have recently ruled against his position while others have agreed with it, setting the stage for a potential Supreme Court resolution.

In an opinion that allowed California resident Leopoldo Duron to continue his

product liability case over an allegedly defective Ventak Prizm 2 defibrillator manufactured by Guidant Corp. (St. Paul, MN), Frank declared that "the FDA regulatory system and a state tort system can and should work together." Guidant's new owner, Boston Scientific, had sought summary judgment on grounds of FDA preemption. In mid-July, Boston Scientific settled the largest class-action lawsuit related to Guidant defects for \$195 million.



Former FDA chief counsel Daniel Troy was known for FDA preemption of state tort cases.

Other class-action suits are pending.

Citing 2004 case law involving a St. Jude Medical product liability case, Frank agreed with Duron and ruled that FDA labeling cannot preempt state law over a risk of which the agency was not aware. There are "triable issues of fact," Frank wrote. He said that among the issues was whether Guidant disclosed the potential for polyamide degradation before being granted premarket approval and whether it appropriately disclosed information to the public after it received reports of failures.

Frank also rejected a Guidant argument that Duron's negligence- and fraud-based claims are preempted because they were allegedly incorrectly premised on the idea that the company had withheld certain information from FDA. Guidant cited precedent from a 2001 case, *Buckman Co. v. Plaintiffs' Legal Comm.* That case involved a claim that FDA had been defrauded by a consultant, Frank wrote, without any claim that the products involved were defective. In the present case, there is



#### Wrap-Up

no fraud-on-FDA claim by Duron; instead, litigation focuses on duties owed to the plaintiff, not FDA.

"In reaching this conclusion," Frank

wrote, "the court is mindful of Guidant's arguments that allowing these claims to go forward will open the floodgates and unfairly stifle medical invention. The court does not see such a harsh result. The FDA regulatory system and a state tort system can and should work together. Each serves different, yet related functions. A regulatory system ensures products on the market have a favorable risk-reward profile, and a tort system provides incen-

tives to manufacturers to develop and maintain safe devices. In this way, private tort remedies strengthen federal standards."

Minnesota federal

judge Donovan W.

Frank: state torts

complement FDA's

regulatory over-

sight of industry.

On June 18, Duron filed a statement of his case in which there are 12 charges against Guidant, including failure to

warn, manufacturing defect, negligence, and fraud. A Boston Scientific spokesman said the company is "fully prepared to take the bellwether cases

to trial and remain(s) confident that when juries look into the individual facts, they will side with us. Guidant defibrillators continue to be among the most reliable in the industry."

Some FDA-savvy lawyers say Frank's ruling is "aberrant." Troy's advocacy, they say, focused on FDA preemption with respect to drug labeling, where there is no statutory preemption, rather than on devices. For devices, there is statutory preemption

against a state having any requirement "different from, or in addition to," an FDA requirement with respect to safety or efficacy. In *Riegel et al.* v. *Medtronic*, the U.S. Supreme Court may reconsider its position that labeling approved in a premarket approval

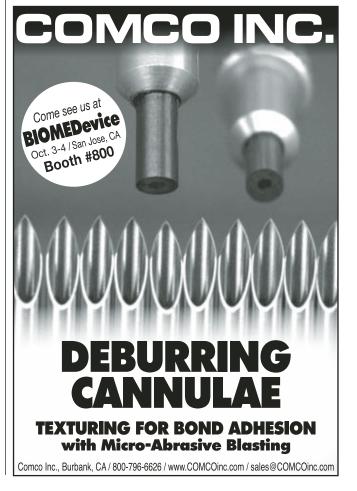
application could not be changed in a tort case, as that would result in labeling "different from, or in addition to" the FDA-approved labeling.

# FDA Extends Deadline for Plant Registration

FDA has postponed the deadline for the annual registration of medical device establishments. A notice in July said the agency expects to resume annual registrations in October or November. Establishments registered for 2007 will have a valid registration until December 31, the notice said.

FDA said it was delaying annual registrations because upcoming changes may significantly affect the way establishments are registered and the way devices are listed. This includes electronic registration and listing, simpler registration and listing requirements, implementation of the Bioterrorism





Act, and congressional consideration of legislation that would impose a registration fee.

# Biolog Accused of Unapproved Marketing

A CDRH warning letter in June to Biolog Inc. (Hayward, CA) says the company is marketing its Biolog Microbial ID/Characterization Fully Automated System without FDA marketing clearance or approval.

The warning letter says the system is considered a device under the Federal Food, Drug, and Cosmetic Act. The definition of a *device* is something that is intended for use in diagnosing disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the body's structure or function. The Biolog system can identify 1900 species of microorganisms.

Biolog has maintained in the past that its device is exempt from premarket review because it should be considered a Class I device. The warning letter says the device is not exempt because there are several important differences between it and Class I devices. The letter did not specify those differences.

The company was given 15 working days to advise CDRH of the steps it was taking to correct the violations.

## FDA Cites Stryker Ireland on QSR

An FDA inspection last fall at Stryker Ireland Orthopaedics's facility in Carrigtwohill, Ireland, found QSR violations in the manufacture of Class II and III sterile orthopedic implants, primarily knee-replacement components, hip-replacement systems, and reconstruction and trauma cable systems.

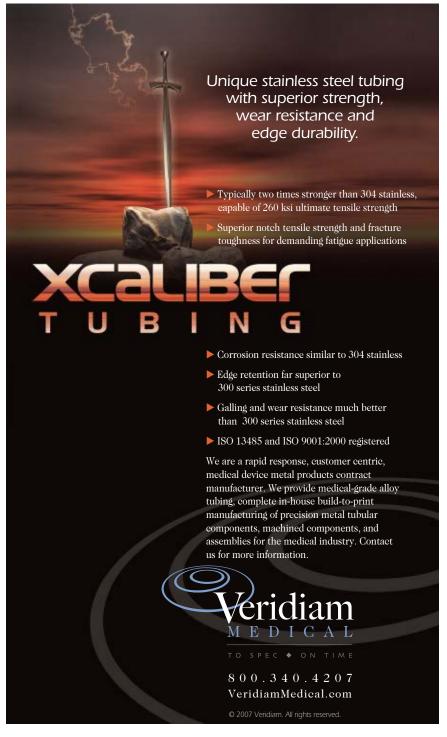
This resulted in a warning letter filed March 15 and released recently. It noted that the firm failed to establish and maintain adequate procedures for:

• Implementing a corrective and preventive action program.

- Controlling product that does not conform to specified requirements, including evaluating nonconforming product.
- Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.
- Rework, including retesting and reevaluation of the nonconforming product after rework, to ensure

that the product meets current approved specifications.

The letter said some of the company's responses were appropriate and adequate, but others were not. Stryker was told to take prompt action to correct all violations, to submit a listing of specific steps being taken, and to explain how the company will prevent violations from occurring again.



# User-Centered Design and the Medical Device Start-Up

Start-ups may have an advantage within the medical device industry because of their innovative ideas. The trick is to use those ideas effectively through user-driven design.

#### Tor Alden

HS Design Inc.

uring the past several years, a substantial number of medical design programs have been initiated by start-up companies. Start-ups are a natural place for such innovation because the companies are characterized by high-risk and high-reward profiles. In almost any hot industry, start-ups attract venture capital (VC). According to market research provided by VentureOne, a VC firm, U.S.-based investments rose 8% in 2006, the highest in five years.<sup>1</sup>

The increased interest in medical design is not surprising considering the number of baby boomers and their demand for new and innovative medical devices. Venture capitalists invested a record \$1 billion in U.S. medical device companies in the second quarter of 2007. That is 58% higher than the second quarter of 2006.<sup>2</sup> The increased need for personalized healthcare products is leading to opportunities for medical device entrepreneurs.

As venture funding funnels its way into development programs, start-up companies are likely to be at the fore-front of providing end-users with medical products geared to their lifestyles. However, for these companies to succeed, they must channel their limited resources into the most-critical needs. One such need is to design products specifically for the user.

With market pressures such as limited funding and time, start-ups need to maximize their development path by initiating user-driven (or user-centered)



design principles. Usability is critical to any product in the healthcare industry. The inclusion of user-driven design enables the team to put specifications on the design parameters, avoiding costly feature creep.

Feature creep is often driven by an OEM's growing wish list, or by designers themselves, as they see opportunities to improve the product. Feature creep is the mistaken belief that one small feature will add zero incremental cost to a project. In all products, there is a temptation to keep adding new features; however, it is important to maintain focus on what the users really need. User-driven design protects against such temptations and also enables the design team to quickly confirm that product concepts address unmet needs in innovative ways.

#### Start-Ups and the Market

User-centered design focuses attention on user needs and is a process used

by traditional Fortune 500 companies. But start-ups differ from Fortune 500s in a number of ways. The obvious differences are in size and in the amount of funds available for product development. However, another difference, not always addressed early on, is that start-ups lack seasoned marketing teams that have access to customer feedback.

Fortune 500 companies spend a great deal of time with customers. They collect feedback and refine ideas in a multifunctional team environment with customer interaction. Fortune 500 firms have dedicated marketing teams that interface with the users and provide a loop back to the design team, conveying issues and concerns facing its customer base. The marketing team also facilitates key meetings between the users and the design team for first-hand observation. This user knowledge is very important.

In contrast, most start-ups are founded on an entrepreneur's idea for a new technology. Some strive to meet an unmet user need. These unmet needs are usually identified by the initial inventor, rather than by a panel of customers. The entrepreneurs often include only a few key people that have a preset perspective on why the product is needed and why it will succeed.

By definition, an *entrepreneur* is a person who undertakes and operates a new enterprise or venture and assumes some accountability for the inherent risks. The entrepreneur is the

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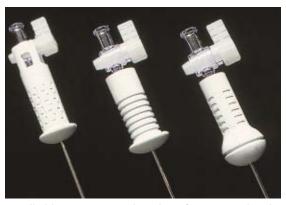
#### Insight

primary product champion, the one voice that has driven the idea past the due-diligence phases of VC funding. This person has likely been consumed by the product idea for a long time and cannot help but develop a set opinion on the design and feature set of it. But even start-ups should take users into account at the outset of the design process.

When embarking on the development path, it is critical to test the product idea on users to gain outside user feedback. Such real-world experiential feedback is critical in determining or validating features important to the device. It is important to test these assumptions with an unbiased group, whenever possible.

#### **User-Centered Design**

There are many aspects to usercentered design, and these should be considered as a product is evaluated for human factors, interface design, and industrial design. Most important



Handheld prototypes, such as these foam surgical tools, may reveal users' unspoken preferences and needs better than visuals alone.

is to identify the relevant use conditions and to understand all key users. User-centered design helps establish and maintain a process for understanding the environment, understanding how users apply the product, and ensuring that the user's needs are addressed. The chief difference from other design philosophies is that usercentered design helps to optimize the product around how people want or need it to work, rather than forcing them to change work habits to accommodate the system or product. This approach aids the development team in creating a product with the potential to

increase market demand and sales because people are more likely to adopt a device that they find easy to use.

The level of design support and the costs required for a design varies depending on the depth and cross-section of people who are interviewed or studied, the device's classification level, and the intended use environment. However, from a very basic level, usercentered design can be an integral part of the design process with minimal effects on budget and time. In many cases, a few carefully selected test users can provide a good base for validating ideas. The cost and time spent on usercentered design is usually recouped because it prevents changes or product redesign late in development. For this reason it is crucial that a start-up use this process if it is operating on a tight budget or schedule.

User-centered design enables a designer to become the user advocate and to serve as the bridge between engineering, manufacturing, and mar-

keting. In general, there are some typical tasks that a user-centered design system should accomplish. These include identifying users, getting meaningful feedback, documenting use environments, developing user scenarios, performing competitive analysis, and conducting usability testing.

Identify the Users of the Product or System. Spending time with the users can help designers find the unmet needs that the en-

trepreneur may not have expressed in the initial product concept presentation to VCs. Suppose, for example, that a new medical instrument can analyze and detect rare cells in blood. All of the focus would be centered on the technology and getting it to market. But how is this new instrument going to fit into its environment? In what area of a lab does it belong? How does the technician manage the blood from the lab? Talking to end-users can help answer these questions. In this case, the technicians are the main users, but there may be secondary users that need to be addressed, such as service or

maintenance personnel. Their responses may be simple (such as finding out users want space on the product for sticky notes) or serious (such as finding out they need to stack a printer on top of the unit).

Get Meaningful Feedback. Finding out what people want is very important for start-ups in particular, because early-stage companies do not always have entrenched marketing, voice-ofthe-customer (VOC) data, or other feedback channels. Established companies use VOC approaches so that the marketing groups can get feedback based on existing products. The downside of VOC is that the information rarely leads to dramatic breakthroughs, but rather encourages incremental improvements. This is primarily because most people have a hard time visualizing or describing better ideas. It is far easier for them to see ideas and then express a like or dislike.

Both start-ups and established companies should invest the time to visualize product ideas for the users to evaluate. Visual ideas help foster early interaction with the users so that companies become familiar with the users' needs. Such insight is critical to the success of the product.

Observe Users in Their Work Environment. An important part of design research is shadowing the user, much as a social anthropologist would do. This includes conducting interviews that ask users what they do and what their experience is with the subject matter. In many cases, the user is a highly trained surgeon, nurse, or technician. But the user could also be a patient.

For start-up device companies launching a new product, it is particularly important to explain the proposed new product. Designers should be prepared to set the stage of what the firm believes the product can do, and then evaluate responses while participants are working with the device. Video ethnography is a good tool to document this experience. Ethnography is a research method founded on the idea that a system's properties cannot necessarily be accurately understood independently of each other. Video ethnography could include sending a small team to videotape the users in their environment without much

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#### Insight

distraction. The video can be viewed and analyzed by a larger team during the course of development. Such data can also be used by start-ups to demonstrate corroboration of users to its VCs through the various gates. A key to



Observing users in their work environment through video ethnography is inexpensive and can reveal daily habits that inform a product's design.

doing design research is to develop a personal relationship with and interest in the people being interviewed. Engaging the users will increase their desire to create a feedback loop for continuing design reviews.

Develop User Scenarios. A great way to address a large population is to create virtual characters and daily-use scenarios. If the product is meant for general use, developing fictional characters can aid in product development and help identify users and their lifestyles. Typical examples of virtual characters might include the following:

- Joe is a weekend warrior who comes to work needing a vacation.
- Emily is a nurse in the emergency room who has 12 patients and the last thing she wants is to learn how to use another instrument.
- Billy is a 12-year-old gamer who forgets his jacket everywhere he goes.
- Dr. Jones is a pathologist who doesn't have room for the equipment he needs.

These are generalized examples with certain assumptions. Ideally, real people are needed to form an idea about product use. But these characters help start-ups understand that products need to fit in the users' lifestyles, not the other way around. The scenarios help justify the appropriate interface, aesthetics, and form of the product.

Conduct Analogous and Competitive Products Analysis. Another simple task that can help in the design process is to compare analogous and competitive products. By listing the competitive products and breaking out their feature sets, designers can create a baseline of features to compare with the new product. Equally, the use of analogous products can stimulate the thoughts of the team by borrowing ideas from other market segments.

Focus on Usability Testing and Discuss Concepts and Prototypes. Concept visualization is one of the most important aspects in uncovering users' unmet needs. Once a product has a user set, it is important to come back to them during the design process and validate the designs.

Users are often more responsive when given a prototype that can be evaluated in person. By comparing multiple concepts and prototypes, users can compare their earlier expectations with the real thing. Prototyping is often the key. The first prototypes can just be foam models for simple evaluation. Each phase has its appropriate prototype level and can be matched with use and available budgets.<sup>3</sup>

#### **Understanding the User**

Users often demand that the product be extremely simple and intuitive to use. For example, the boomer market is an important driver in medical innovation. Boomers expect medical devices to span the gap between medical equipment and consumer products. Questions that start-ups should ask include the following:

- What are the users' physical limitations or characteristics?
- How familiar with technology are users?
- What are users' skill sets?
- What are the motivations of the user with regard to compliance?
- How often will users need the product?
- How much training is required?

Understanding users is critical to the development of the product's interface, form factor, and appropriate use of aesthetics. Such design research is an inexpensive way to validate that the design meets its users' needs. Designers are engaged with the users for short periods of time. The money spent can be as basic as the cost for travel, time on-site, and a videotape. For patients, a small honorarium may need to be provided. Doctors and nurses are often willing to donate their opinions and time to a project that has the potential to improve their work.

#### Conclusion

It can be difficult to marry the needs of the manufacturing process with the needs of the user. Medical device startups should consider that their product may require high-volume manufacturing (a significant topic that is beyond the scope of this article). At the same time, users want simple and elegantly designed products that are easy to use. In addition, start-ups need to understand that, by definition, the user's unmet need may not be known prior to the research.

By getting the design team up to speed quickly and confirming the design direction throughout the program, user-centered design helps increase speed to market and can help avoid costly design changes. Design-centered research helps refine the initial idea and tailors it to fit the environment and users' needs. This approach can also assist a start-up in validating the idea as it navigates through the various rounds of VC funding.

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## Postmarket Vigilance in Europe: New Guidance for Manufacturers

New European medical device postmarket vigilance guidelines have been published. By the end of 2007, manufacturers selling in Europe should update their quality systems to comply.

#### **Roger Gray**

Donawa Consulting

The European Commission has recently published an updated guidance on the postmarketing vigilance requirements for medical devices. All medical device manufacturers placing medical devices on the European market should obtain a copy of the new guidelines and ensure that their procedures for reporting incidents are brought into line. The new guidelines reference the following three directives:

- Active Implantable Medical Devices (AIMD) Directive, 90/385/EEC.
- Medical Devices Directive (MDD), 93/42/EEC.
- In Vitro Diagnostic Medical Devices Directive (IVDD), 98/79/EC.

The guidance has been updated from the April 2001 version to add further detail in the light of experience from the national competent authorities (NCAs) of member states. It includes specific information relating to in vitro diagnostic devices and takes into account regulatory guidance documents on vigilance and postmarket surveillance published by the Global Harmonization Task Force (GHTF).

The guidelines have been issued as a revised medical devices (MEDDEV) document, reference 2.12-1, rev. 5, dated April 2007. They were published on the European Commission Web site in June 2007. The guidelines have been virtually rewritten from the



2001 version, with changes to some of the basic terminology and the inclusion of new definitions. Some of the ideas within the document are taken from the publications of Study Group 2 of the GHTF.

From a manufacturer's point of view, the new guidelines are stricter on the timing for reporting incidents. They also contain new reporting concepts, including periodic summary reporting and trend reporting.

Terms that have disappeared from the guidelines include *advisory notice*, *near incident*, and *recall* (aside from a passing reference).

Although the MEDDEV documents are not legally binding, and adoption as national guidelines by member states is not guaranteed, it is likely that all NCAs will expect manufacturers and their authorized representatives to comply. The guidelines are effective

January 1, 2008, with a transitional period ending December 31, 2007, allowing for gradual implementation by affected organizations.

#### **Applicability**

The applicability of the reporting rules in the new document has been expanded to include: "Devices that do not carry the CE mark because they were placed on the market before the entry into force of the medical devices directives," whereas the previous version was applicable only to "devices that do not carry the CE mark, where such incidents lead to corrective action relevant to CE-marked devices." This brings devices that were designed, manufactured, and marketed before publication or implementation of the directives within the guidelines. This change may be controversial because, by association, it extends the scope of the vigilance requirements to devices placed on the market prior to the directives becoming law.

The guidelines have also been extended to include "devices that do not carry the CE mark but fall under the directives' scope," which would include custom-made devices and devices being used for clinical investigations. These products were specifically excluded from the scope of the 2001 guidance, although a footnote explained that "incidents occurring during clinical investigations meeting the same criteria as those reportable under the Vigilance

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#### Regulatory Outlook

The MEDDEV document includes a number of new terms, which are reviewed and discussed in Table I.

#### What and When to Report

The identification of an event that must be considered an "incident," and therefore must be reported, has been clarified. Table II lists the basic criteria that must be met for an event to be treated as an incident.

The definition of serious deterioration in the state of health has been exof a field safety notice (FSN), or for well-documented incidents already identified in the manufacturer's risk analysis, once initial reports have been evaluated by the NCA. For the already-identified incidents, trigger levels for interim reporting should be agreed upon with the NCA.

The previous timescales of 10 days for reporting incidents and 30 days for reporting near incidents (which were modified by some member states in national legislation) have been re-

NEW TERM	COMMENT
Abnormal use	Taken from IEC 60601-1-6 on "Usability," essentially defining what was usually referred to previously as user error. <sup>2</sup>
Field safety corrective action (FSCA)	Replaces recall.
Field safety notice (FSN)	Replaces the term <i>advisory notice</i> . Previously, <i>advisory notice</i> included both the written notification to the user and an explanation of the corrective action undertaken, whereas now the FSN will advise what FSCA should result.
Incident	Defined as in Article 10 of the MDD. Note that <i>near incident</i> is no longer used to indicate an event that did not result in a serious clinical outcome but may do so if repeated. Under the new guidelines these are treated the same as incidents and must be reported as such.
Indirect harm	Introduced to take into account diagnostic devices, including IVDs, which do not act directly on the individual, covering, for example, misdiagnosis and inappropriate treatment.
Periodic summary reporting/Trend reporting	Included as reporting options under certain conditions, taking a lead from the GHTF.
Unanticipated	Linked to the manufacturer's risk analysis—if the circumstances that led to an event were not considered during risk management, then this event is considered "unanticipated."
Use error	Not to be confused with <i>user error—use error</i> could also include events resulting from errors by the manufacturer, such as omissions or mistakes in instructions.

Table I. Explanations of the new vigilance terminology from the European Commission's updated guidelines.

panded to include any "indirect harm" as a consequence of incorrect diagnostic or IVD test results.

Under the revised guidelines, NCAs could accept periodic summary reporting of incidents from manufacturers once one or more initial reports have been submitted and evaluated by the NCA. Periodic summary reporting may also be appropriate for reporting incidents that occur after the issuance

placed. The new wording indicates that reports should be filed as soon as the manufacturer becomes aware of an incident, but with maximum time periods, as shown in Table III.

The conditions under which reporting is not required have been expanded and clarified with no significant changes, although one reason has been removed (see Table II). The one condition that has been removed concerns



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#### Outlook

removed (see Table II). The one condition that has been removed concerns incidents that occur after an FSN has been issued. These may now require periodic summary reporting. Manufacturers should, however, monitor such events. Upon identifying any significant increases by means of trend reports, manufacturers should inform the NCA of the increase, regardless of whether periodic summary reporting has been agreed upon with the NCA.

Abnormal use need not be reported, but use errors that actually result in death or a serious deterioration in the state of health are reportable. Use errors that may result in death or a serious deterioration in the state of health become reportable if a significant increasing trend is noted, or if the manufacturer initiates corrective action to avoid such incidents.

#### **Access to Suspect Devices**

The section relating to access to suspect devices has been expanded to sug-

gest that if a manufacturer's initial assessment of the device may require altering it in any way, then in requesting the NCA's permission to proceed, the manufacturer should include a timescale for reply, along the following lines: "We assume destructive analysis can begin 10 days from the date of this report, unless the NCA contacts the manufacturer within this timeframe, opposing destructive analysis."

#### Format of Field Safety Corrective Actions and Field Safety Notices

The section previously titled "Systematic Recalls" is now called "Field Safety Corrective Action (FSCA)." This section includes advice to manufacturers to use the methodology described in EN ISO 14971:2000 in their assessment of the need for FSCA. However, manufacturers should clearly use the most recent version of the standard (currently, the 2007 edition).<sup>3</sup>

The recommended format of the initial report to the NCAs is more detailed

than the previous version. In addition to answering the questions on the form, the manufacturer is advised to include copies of other documents, including relevant extracts from the risk management file, whether the resulting action is corrective or preventive, advice to users and distributors, and a copy of the FSN.

The MEDDEV document suggests that a draft of the FSN should be submitted to the relevant NCA prior to release, allowing 48 hours for comments to be received. The previous MEDDEV contained little guidance on what should be included in an FSN, but the new document puts forward comprehensive advice for manufacturers, including a recommendation to use company letterhead paper and a clear title, with the words "Urgent Field Safety Notice." A factual statement that explains the reasons for the FSCA, along with what actions should be taken by the users of the device should also be included.



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REPORT REQUIRED?	OCCURRENCE
Report an incident when	An event has occurred, AND
	the device is suspected to be a contributory cause, AND
	the event led to or might have led to either:
	<ul> <li>the death of a patient, user, or other person; or</li> <li>a serious deterioration in the state of health of a patient, user, or other person.</li> </ul>
Do not report an incident when	Device deficiencies are found prior to use.
	The event is caused by patient conditions.
	The device's service or shelf life has been exceeded.
	Correct functioning of the device feature providing protection against a fault occurs.
	Expected and foreseeable side effects occur.
	There is a negligible likelihood of death or serious deterioration in state of health.
	The event is a result of abnormal device use.

Table II. Reporting criteria for an event to be treated as an incident.

down the level of risk in an inappropriate manner must be excluded, as must any advertisements for products or services.

Finally, the guidance suggests the use of an acknowledgement form for the users to return to the sender, thereby allowing the manufacturer to demonstrate that the user group has received and acted upon the FSCA.

#### NCAs, the European Commission, Notified Bodies, and Users

The role of NCAs has not been altered significantly, and it still includes the possibility of monitoring of the manufacturer's investigation and subsequent actions, together with notified bodies, other NCAs, and additional organizations, such as test houses.

The 2001 MEDDEV was silent on the roles within the vigilance system of the European Commission and notified bodies, but the new guidelines include brief overviews of their responsibilities and supporting activities.

Healthcare organizations, such as hospitals and other clinical facilities, were mentioned in the earlier edition as playing a vital role in providing the first link in the vigilance chain, even though there are no legal responsibilities on them under the directives concerned. The revised document explains this lack of a legal requirement, but stresses that only with the close in-

volvement of users can the implementation of effective postmarketing corrective and preventive actions be achieved.

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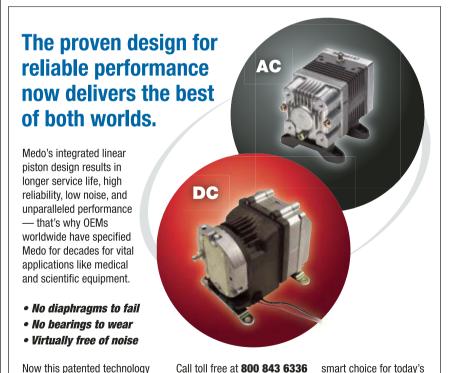
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An annex to the new version of the guidance provides advice to manufacturers that would result in a greater involvement of users in vigilance activities to ensure the most efficient and effective outcomes. Other annexes include templates for an initial report form, an FSCA report form, an FSN, and a form for exchange of information between NCAs.

#### Conclusion

The new guidelines contain some controversial aspects, including the extension of their scope and the new approach of immediate reporting unless delays can be justified. However, they also provide additional clarity and more-detailed advice in many areas. Periodic or trend reporting under certain conditions is now allowed, as a result of the integration of certain GHTF concepts.

Although a transition period is allowed until the end of 2007, the revised guidelines will undoubtedly result in the need for manufactur-



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#### Outlook

ers, authorized representatives, and distributors to quickly make substantial changes to their standard operating procedures (SOPs) and other documents. Materials requiring revision may potentially include the following:

- Quality manual.
- Complaint-handling SOP.
- Incident-reporting SOP.
- Recall, field corrective action, and advisory notice SOPs.
- Clinical investigation SOP.
- Authorized representative agreements.
- Distributor agreements.

Manufacturers marketing medical devices in Europe, as well as their distributors and authorized representatives, urgently need to review the revised guidance document in detail. It is essential that manufacturers make the necessary changes to their quality management system and are ready to implement the

INCIDENT TYPE	REPORTING TIMESCALE
Serious public health threat.	Immediately, and no later than 2 calendar days after awareness of the threat by the manufacturer.
Death or unanticipated serious deterioration in state of health.	Immediately after the manufacturer establishes a link between the event and the device, but no later than 10 calendar days after the manufacturer's awareness of the event.
Other incidents.	Immediately after the manufacturer establishes a link between the event and the device, but no later than 30 calendar days after the manufacturer's awareness of the event.

Table III. Reporting timescales.

new postmarket vigilance reporting guidelines beginning in January 2008.

#### References

- MEDDEV 2.12-1, rev. 5, "Guidelines on a Medical Devices Vigilance System" (Brussels: European Commission, 2007 [cited 19 July 2007]); available from Internet: http://ec.europa.eu/enterprise/medical\_ devices/meddev/2\_12\_1-rev\_5-2007.pdf.
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- cal Equipment—Part 1-6: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Usability" (Geneva: International Electrotechnical Commission, 2004).
- ISO 14971, 2nd ed., "Medical Devices— Application of Risk Management to Medical Devices" (Geneva: International Organization for Standardization, 2007).





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# Tube Manufacturing Made Easier

Medical device firms have much to gain by considering the manufacturability of tubing designs.

William Leventon

any design decisions affect how easy or difficult it will be to manufacture a tubing product. But often, designers aren't aware that their choices can lead to unavoidable manufacturing difficulties.

In many cases, design decisions lead to hard-to-meet requirements that aren't actually needed for the tubes to perform their intended functions. Such decisions relate to, among other things, the choice of materials, the configuration of part features, and the dimensions and tolerances assigned to parts.

So whether they do it in-house or with the help of their manufacturing partners, medical device firms can save significant amounts of time and money by evaluating the manufacturability of their tubing designs and modifying or eliminating requirements that unnecessarily complicate the manufacturing process.

#### **Material Questions**

For each tubing application, manufacturability evaluation should be performed. By asking—and honestly answering—a number of key questions in the area of materials OEMs can better assess their critical needs.

Are we making extraordinary demands of our tubing material? If so, manufacturing personnel may find it difficult if not impossible to meet those requirements. "Some design engineers want everything. But one plastic can't provide all that they want," says Krissi Heard, who handles technical sales for MicroLumen Inc. (Tampa, FL). The company manufactures custom polyimide tubing primarily for minimally invasive medical devices. When dealing with overly demanding designers, MicroLumen tries to get them to

William Leventon is a freelance writer based in Somers Point, NJ, who frequently contributes to MD&DI.



Polyimide materials are among those often used in device manufacturing. Photo courtesy of MicroLumen Inc. (Tampa, FL).

zero in on their most critical requirements to see whether these can be met by polyimide.

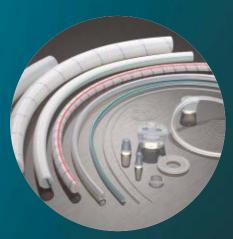
Do we have good reasons for choosing that material for our product? Many medical device firms now want tubing made of exotic metals such as platinum, nickel alloy, and titanium, according to Vin Altruda, vice president of manufacturing for Popper Precision Instruments Inc. (Lincoln,



In many cases, design decisions lead to hard-to-meet requirements that aren't actually needed for the tubes to perform their intended functions.



It is important to choose the material that is best for the product. Photo courtesy of Advanced Polymers Inc. (Salem, NH).



Platinum-cured silicone tubing can be molded and extruded into a variety of components. Photo courtesy of Helix Medical Inc. (Carpinteria, CA).



It takes time to develop a formulation that produces the desired color when extruded. Photo courtesy of Advanced Polymers.

Braid-reinforced polyimide tubing such as this from MicroLumen (Tampa, FL) provides increased column strength and torque transmission.



Custom tubes, like these from Precision Extrusion Inc. (Glens Falls, NY), can be created for medical device manufacturers.

RI). His company fabricates metal tubing for applications such as analysis equipment and gluing machines used in medical device production. But production can be more difficult when designers choose something other than standard metals such as stainless steel, which is by far the most common tubing material Popper works with in its fabrication operations.

For one thing, Altruda says, manufacturers may have a hard time finding sources for unconventional metals. In addition, he notes, manufacturing personnel and operations that deal mainly with stainless steel may find it difficult to process other materials. "As our customers go to more exotic materials, we have to learn how to process them," Altruda says. "And many times, we can't do it with the equipment we have."

According to Altruda, titanium is the most popular of the new alternatives to stainless steel. But Popper has found titanium harder to work with than stainless steel. In fact, the firm has yet to figure out how to perform some of its normal fabrication operations on titanium. So Altruda and his colleagues will sometimes ask customers if stainless steel can be substituted for titanium in their designs.

As for plastic tubes, many designers choose a material because they've used it before and know it—not because they've determined that it's the best plastic for their current product, maintains Mark Saab. He is president of Advanced Polymers Inc. (Salem, NH), which manufactures plastic tubing and medical balloons for dilation procedures. As a result, the chosen plastic may be difficult to obtain, which can

slow the manufacturing process. Or it may only be produced by a supplier whose materials often have inconsistent properties.

"We've seen a lot of batch-to-batch variation in some materials from certain suppliers," Saab says. "That makes it harder for us to run the materials and harder to meet the customer's dimensional requirements."

Is that additive necessary? Saab's customers often ask that their tubing include a barium sulfate filler for radiopacity. But such fillers can't be added in Saab's manufacturing machines. Instead, he says, they must be mixed into the tubing material in a special compounding step, which adds a considerable amount of time and expense to the manufacturing process.

Generally speaking, Saab says, Advanced Polymers can extrude a Pebax tube in two weeks. But if a customer wants a Pebax tube with 20% barium sulfate, there might be three or four weeks of lead time spent waiting for a compounder to acquire the required materials, mix them, and deliver the finished product. To make matters worse, he adds, the custom compound might double the cost of the job.

So what are the reasons for the addition of this troublesome filler? "Some people say that they need it because marketing asked for it. Other people say they don't know why they need it, but a competitor's product has it, so they want it. But many times, the competitor's product is 10 or 15 years old and [the radiopacity] isn't important anymore. So when we get done talking to them, they'll say, 'I guess we don't need it,'" says Saab, who has talked many customers out of adding radiopaque fillers to their products.

# Extrusion of complex or irregular tubing geometries can be seriously affected by lot-to-lot variations in silicone materials.

Can you get by without a special color? According to Saab, many device manufacturers want tubing of a specific color—to match their corporate colors or for some other reason. But when material with colorant is extruded into a thin-wall tube, the resulting color will look much lighter than the colorant did to begin with. If a customer insists on the darker shade that was originally requested, the result can be a time-consuming trial-and-error process. It can take time to come up with a formulation that will produce the desired color when extruded. In development, this process can add weeks to the lead time and increase the cost of an extrusion run by 50–100%, Saab says.

Today, however, Saab extrudes many tubes that are clear or a natural color. The designers of these products aren't concerned about color because the tubes, which are used in tiny devices, are so small that "you can hardly see the product anyway," he says.

How well will those two materials work together? Today, designers often integrate other products into their tubes,



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notes Sean McPherson, vice president of marketing for Helix Medical Inc. (Carpinteria, CA), an extruder of silicone tubing. For example, some of the company's customers want silicone tubes with electrical wires inside the walls. Used for communication, the wires carry signals in diagnostic or monitoring systems.

On the downside, dual-material tubes can create serious manufacturing problems. For instance, McPherson says, some types of wire have so much shape memory that they'll deform or even push through the walls of silicone tubes being created around them. But other wires work better, so designers of these products must know enough to pick the right type or seek help from contract manufacturing partners knowledgeable about silicone extrusion.

Silicone is also being combined with Teflon and other materials to create tubes with multiple properties. Designers of these tubes must be sure that whatever material is paired with silicone can take the 350°–450°F temperatures that silicone is exposed to during its curing process, McPherson notes. In addition, he says, they must be sure the other material will bond to silicone or can be attached to it using a special coating or pretreatment.

#### Sizing Up Part Features

In addition to material-related matters, designers should carefully consider the manufacturability of their tubing features. Important questions in this area should encompass both physical and cost considerations.

Is this bend radius too small? Stainless-steel hypodermic tubing kinks if the radius of a bend isn't at least twice the outside diameter of the tube, says Altruda.

Is that too much reduction? Sometimes, medical device designers want to reduce the diameter of a piece of metal tubing somewhere along its length. For example, Altruda says, a designer might want to reduce the diameter at the end of a tube to create drops of a certain size. Popper can do this using a rotary swaging operation that proportionally reduces the outside and inside diameters at one end of a tube by running it through a set of dies. But some customers ask for reductions that can't be accomplished using normal manufacturing operations. Although it may be possible to produce the reductions using unconventional processes, "we'll talk to them to find out whether they can live with something that's more manufacturable," Altruda says.

Why do we want sharp corners? Design drawings of multilumen parts often show sharp corners on D- and crescentshaped lumens, says Michael Badera. He is president of Precision Extrusion Inc. (Glens Falls, NY), which designs and manufactures custom plastic tubing for the medical device industry. But in a normal extrusion process, Badera notes, plastic doesn't flow in a way that allows the creation of sharp corners. To produce these features, he says, manufacturers must embark on a complicated process that includes difficult tooling design.

Why do tube designs include sharp corners? Designers may think they allow a little more flow through the tube

than rounded-off corners, Badera says. "But in reality, there won't be good flow through those areas anyway. So it looks like they're giving up some real estate [by rounding off the corners], but I don't believe it's actually affecting the flow."

Are complex shapes worth the trouble? Under certain circumstances, tooling can cost five times more than it normally would for silicone extrusion, says Chris Hamming, a manufacturing engineer at Helix Medical. This can happen when designs call for two features. One is when lumens are D-shaped, curved, oval, square, or some other shape that isn't circular. The other is when designers need arrangements of circular lumens that aren't in a symmetric pattern, he explains. "Setup can go from a typical half hour to half a day or half a shift," he says. "That's the worst case, but we see it."

In addition, compared with normal geometries, extrusion of complex or irregular tubing geometries can be more seriously affected by lot-to-lot variations in silicone materials. "We may have all our parameters dialed in," Hamming



Metal tubing can be used in analysis equipment and machines used in medical device production. Photo courtesy of Popper Precision Instruments Inc. (Lincoln, RI).

says. "But if we go to run the same part with the same die and mandrel three months later, we find ourselves having to do a lot of tweaking."

Are we willing to pay the price for very small features? Hamming says that creation of internal silicone tube features measuring 0.007 in. or less can double or triple lead time. It can also cost up to four times more than it does to produce larger silicone features, according to McPherson.

#### The Big Question

Of all the manufacturability questions that can be asked about a tubing design, perhaps none is as important as this one: How manufacturing-friendly are the design dimensions and tolerances?

Among tube designers, Hamming says, "there's a tendency to overspec—to impose minimum wall thicknesses and small tolerance ranges on features that aren't critical." When designers pile on features, requirements, and restrictions in a single tube design, he adds, manufacturers can "end up with almost nothing left to work with. The part has to be almost perfect."

Badera thinks overly tight dimensional restrictions can be attributed to a lack of knowledge about plastics. "With



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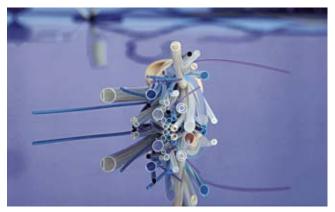


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Visit www.Orchid-Orthopedics.com to see how your business can build on our industry strength. fabricated parts made of metal, you can grind and drill and ream very precisely—in some cases down to tens of thousandths of an inch," he says. "And a lot of designers think plastic tubing is just like metal tubing—that you can specify things out to four decimal places and hold tolerances of plus or minus almost nothing. Unfortunately, plastic extrusion doesn't work that way."

Sometimes, Badera's customers make his job even more difficult by presenting him with what he calls "conflicting tolerances." For example, consider a tube with an outside diameter measuring 4 mm, a 1-mm wall thickness, and a 2-mm inner lumen. If the specification for this tube calls for a tolerance of  $\pm 0.1$  mm for the outside diameter and  $\pm 0.05$  mm on the inner lumen and the top and bottom walls, an extruded tube wouldn't meet the OD specification if all the



It is important to choose a tubing because it's optimal for the intended product. Photo of extruded tubing courtesy of Advanced Polymers Inc. (Salem, NH).

component dimensions were at the high end of their tolerance ranges. (The tube would require an OD of 4.15 mm versus the specified tolerance of 4 mm + 0.1 mm.)

In this case, Badera says, "[the supplier is] not given room to work with all the specs in their full range. It has to work tighter than the  $\pm 0.05$  mm tolerances or the OD will be out of spec."

Besides making manufacturing extremely difficult, overly tight tolerances can drive down the yield of the production process. "If we're asked to hold a tolerance of  $\pm 0.001$  in., we have to throw away everything that's outside that spec, which could be 50% of the product being extruded," Saab says. "I've seen jobs run at 50% yield in production that could have run at 90–100% yield if the tolerance had been opened up by 0.001 in."

#### Hearing from the Manufacturer

So before they dig in their heels on dimensions and tolerances, designers might benefit from a talk with their manufacturers. For example, at no additional cost, Precision Extrusion will review specifications with customers to help them determine which items are really important and which are not. "Most of the time when we talk to customers, we find that they can loosen up the tolerances on several dimensions," Badera says. "They just hadn't thought about what's really critical to their designs."

If Altruda and his colleagues spot tolerances that will be difficult to hold, they sometimes point out to customers that opening up the tolerances will make their products less expensive to manufacture. In such cases, most customers allow tolerance changes, Altruda reports.

When Helix quotes jobs with tight tolerances, the company provides customers with options that show how much they can save by relaxing certain tolerances. "We're usually pretty successful when we show them that there's a big [cost] difference between what they're asking for and what they might really need," McPherson reports.

Despite the obvious advantages for both parties, however, manufacturability discussions between tube designers and manufacturers seem to be the exception rather than the rule. Why aren't they more common? McPherson speculates that some designers may not solicit outside manufacturability input because it adds to design time, while others may be unwilling to share design information with another firm. Badera attributes it in part to procedures at large firms that tend to produce designs that are "pretty much set in stone."

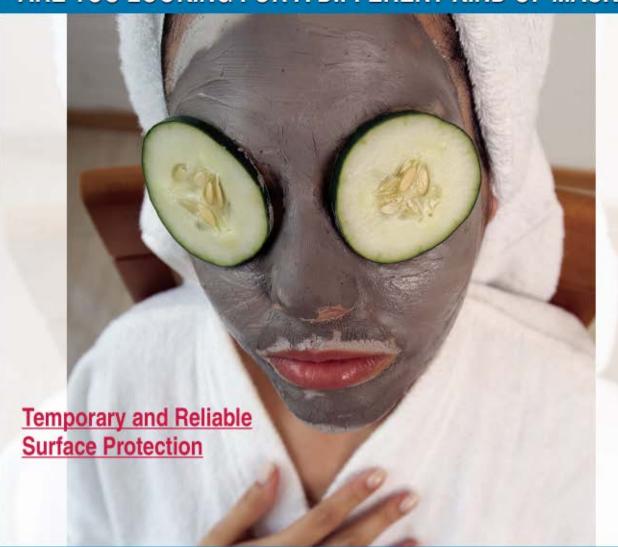
If many tube manufacturers had their way, designers would come to them early and often for manufacturability input. For example, Badera says, "A customer might come to us with his first idea and say, 'What do you think?' And we would say, 'This wall is too thin, this one is too thick, and your tolerances here are too tight.' Then the customer would come back to us with second and third iterations, and the two of us would keep working through these issues until it got to the point where we'd say, 'That's very doable,' and the customer would say, 'Good. I think it will work for me.'"

For example, Radiant Medical Inc. (Redwood City, CA) enlisted Advanced Polymers's help during the development of Reprieve, Radiant's device for controlling patient temperature. The product includes a heat-exchange balloon catheter that maintains a small profile during placement in the patient's body and then expands to maximize heat transfer between the blood and the catheter. The balloon catheter includes three helical lobes that exchange heat with blood flowing over their surfaces. Sterile saline circulating through the balloon catheter is warmed or cooled as necessary to produce the desired patient temperature. This heat-exchange mechanism allows the saline to change the temperature of blood without actually coming in contact with it.

Radiant collaborated with Advanced Polymers to create the balloon catheter. "We involved them basically from the get-go," recalls Ben Brian, Radiant's vice president of engineering. "We drew some designs literally on the back of a napkin and said, 'What do you think?'" During the development process, the team reduced the catheter's lobes from seven to three so that the job could be completed within Radiant's time frame. The process "was very iterative and collaborative, with good theoretical analysis on our end and good practical analysis on their end."

What's the lesson from this successful partnership? "It's critical to involve the supplier and not just throw a specification over the wall," Brian says. "Collaboration is the key to manufacturability."

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# Deciphering Requirements for Environmental Testing

Manufacturers should keep bioburden in mind at all times and use ISO 14644 and ISO 14698 to help satisfy environmental monitoring and testing requirements.

Scott Mackin

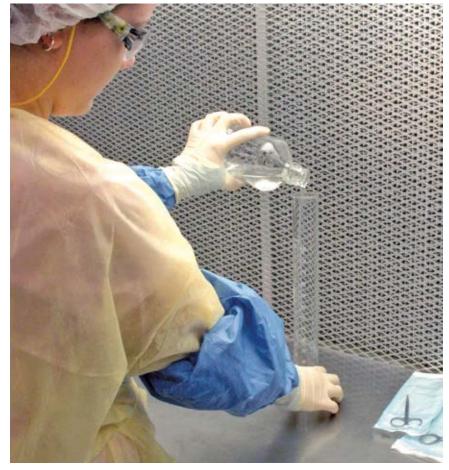
ndustrial sterilization and contamination control programs are critical to medical device manufacturing. This article reviews the key elements of a best-practice environmental testing program, including sterilization standards and the critical factors in maintaining controlled environments.

#### The Challenges of Environmental Requirements

One of the biggest challenges facing medical device manufacturers in designing, implementing, and maintaining their sterilization and environmental monitoring programs is determining what exactly is required for compliance.

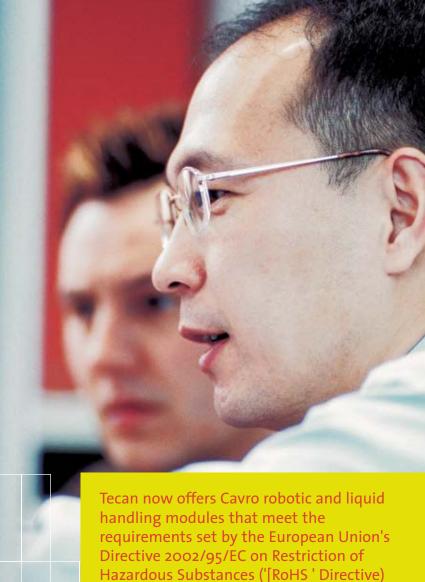
For parenteral manufacturers, environmental control parameters are stringent. A collaborative effort between the FDA Office of Compliance in the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Office of Regulatory Affairs produced a guidance, "Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice."

Scott Mackin is a project manager at Microtest Laboratories Inc. (Agawam, MA).



A technician at Microtest performs bioburden testing using the aseptic technique. There are no commonly accepted levels of environmental bioburden.

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By contrast, device manufacturers have to piece together a coherent and defensible strategy by choosing bits and pieces from different standards, guidance documents, and corporate policies. For small or inexperienced device manufacturers, the task is daunting, and they might only know the strength of their program after it has been reviewed or audited externally.

If and when environmental controls are implemented, companies often have little confidence in their practicality or that the programs will pass regulatory muster (i.e., an FDA audit). When employees do not buy into the value of the program, it often results in a system of documenting control failure rather than a program that demonstrates continued control and compliance.

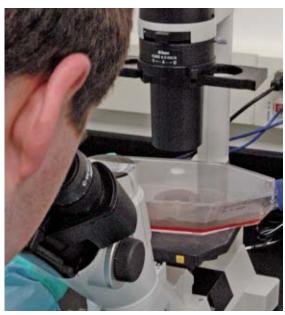
In most cases, this will negatively affect the entire environmental system, ultimately resulting in loss of production.

Large companies often have solid programs in place for commissioning new production areas, continued monitoring, and sterilization validation. Additionally, because many of these companies are experienced in satisfying a variety of regulatory requirements to market their products globally, their programs tend to be more comprehensive.

#### Particulate Characterization: Viable versus Nonviable

Since the early days of Federal Standard 209 (FS 209), cleanliness classes have been assigned to clean zones using measured levels of nonviable particulates. Microbiologists and regulatory professionals initially struggled to draw a correlation between the levels of nonviable particles and viable particles present in the environment. They concluded that no direct relationship could be defined. However, because of the relative ease and practicality of continuous monitoring for nonviables, it remains the most reliable method for real-time assessment of environmental control.

With the exception of Class 100 (ISO Class 5) areas, there is a lot of ambiguity in determining what satisfies the



Ideally, data collection and analysis should correlate bioburden, product contamination, and sterilization efficacy.

microbial sampling requirements called out in many standards. There are no commonly accepted levels of environmental bioburden, especially in Class 10,000 (ISO Class 7) and Class 100,000 (ISO Class 8) areas. Because FS 209 expired and ISO 14644 has taken its place, ISO 14644 is recognized as the current standard for the design and validation of controlled environments.1 In addition, ISO 14698 provides manufacturers with concrete guidance in setting up the microbial portions of their programs.2 Still, it stops short of providing a definitive method for determining just how much microbial sampling is sufficient. Many manufacturers use the same calculation for their microbial sampling that is set forth in ISO 14644 to sample for nonviable particulates. Even so, there is no indication of what sample locations in the environment are most critical and which types of organisms (e.g., aerobic, anaerobic, fungal) must be recovered. Sampling requirements are open to interpretation, and written justification for a firm's sampling procedures must be provided in its overall environmental monitoring plan.

Unfortunately, as sterilization validation programs rely more and more upon bioburden control and monitoring, these missing pieces become even more critical. If possible, manufactur-

ers should evaluate methods of collecting and analyzing data that could correlate environmental bioburden, product contamination, and sterilization efficacy.

#### **Sampling Plans**

Regulatory agencies generally defer to a table or calculation for determining sampling frequencies and volumes. Often manufacturers must design an environmental sampling scheme by identifying critical areas of product contact or manufacturing activities. At first glance, oversampling sounds like an easy solution. But for many manufacturers, it is simply not a feasible approach with respect to budgetary or personnel resources. The expense associated with purchasing, validating, and

maintaining sampling equipment, plus buying supplies and training personnel, is often prohibitive. In addition, many sampling schemes and control parameters are only verified quarterly or semi-annually as set forth in ISO 14644, especially in Class 100,000 areas.<sup>3</sup> For small and start-up medical device companies, it makes sense to outsource—that way they can draw on resources and expertise that might be too expensive to staff internally.

#### Validation: Controlling Costs and Understanding Requirements

Testing firms can help manufacturers develop a tailored monitoring program that is both fiscally reasonable and able to withstand external audits.

Before a cleanroom is commissioned, it's necessary to plan for the collection of data required for validation, as well as the source of those data. Vendor responsibilities need to be clearly defined, managed, and documented in an agreement to avoid costly retesting. Having a clear understanding of the regulatory requirements and managing vendor activities effectively shortens project timelines, reduce expenses, and jumpstart production. ISO 14644 offers an overview of important performance parameters. It also provides guidance including requirements for start-up and qualification.4



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#### Sterilization Method Selection

The method of selecting the most appropriate environmental monitoring and terminal sterilization programs should not only be a function of process method (e.g., gamma versus ethylene oxide); it should also take into account the level and nature of both the environmental and the product bioburden.

Device manufacturers have increasingly become aware of the importance of the relationship between their environmental monitoring and sterilization programs. This is especially true given the increased use of the VD<sub>max</sub> method for sterilization validation. In fact, ISO 11137, ISO 11737, ISO 13409, and AAMI TIR-33 all refer to the need to have an environmental monitoring program in place.

The  $VD_{max}$  method for gamma sterilization validation and control was developed by established manufacturers in the industry with numerous historical data regarding the normal ranges of environmental and product bioburden.



Testing firms can help manufacturers establish training programs and protocol for working in a controlled environment.

It reduces costs associated with testing by reducing the number of samples required for sterility release (testing is damaging to product). The verification dose (release) test is performed at a high dose, decreasing the risk of failure at 25 kGy, a common dosing value.

It was easy for the experienced manufacturers to document their justification for using this method because they could review previous trends and had a good understanding of what could be considered a state of control. Such manufacturers already felt confident that the environmental programs they had in place were sufficient to support product bioburden control, reducing the potential of verification dosing failures. Now more and more start-up firms and component manufacturers are using the  $VD_{max}$  method for new product sterilization validations.

#### **Bioburden Control**

The use of the VD<sub>max</sub> method reduces the amount of product required during quarterly dose audit testing, which in turn reduces the annual cost of product release testing. This makes the method especially attractive to start-up manufacturers. However, this method is not always the best option, especially for companies with limited experience with controlling bioburden. AAMI TIR-33 states that this method cannot be used when the estimated average bioburden exceeds the limit for the selected sterilization dose.<sup>5</sup>

Cost and product savings can quickly vanish during quarterly audits if there are high bioburdens. It is important to remember that the verification dose is performed at a sterility assurance level of 10<sup>-1</sup>, which indicates the probability of a microorganism being present on product after it has been sterilized. The dose is performed on a statistically smaller sample set.

An influx of unobserved resistant organisms can ultimately result in retests, if not revalidation—even in situations in which the bioburden count does not increase over historical levels. This makes understanding the nature of the typical bioburden as important as the levels themselves. Trending seasonal bioburden variations and identifying in-house isolates are two examples of how to gain this understanding.

#### **Other Critical Factors**

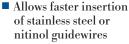
A number of other factors not always obvious to manufacturers are vital to an effective bioburden control program.

Raw Materials. Precautions should be taken to ensure that external

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bioburden does not travel into the production areas along with components and materials. Although specifications will vary, these materials should usually be removed from the original shipping containers and cleaned with a non-residue-forming disinfectant.

However, the level of disinfectant activity required is a function of the cleanliness class and its associated requirements. All materials should be stored for staging in controlled areas within or adjacent to manufacturing suites. In addition, every effort should be made to reduce or eliminate cardboard and paper products from the controlled environment. Process flow should be clearly defined and qualified. Adhering to a plan helps manufacturers avoid surprises and deal with unknowns.

Personnel Training. There should be written and posted procedures for proper gowning and hand washing, and the basic microbiological principles involved in minimizing contamination should be understood by manufacturing personnel. Elements such as the location and placement of equipment and operators can significantly affect the risk of product contamination.

Some laboratories help manufacturers establish protocols for use in personnel training. Training documentation should be in place for all personnel who will work in the manufacturing area. For example, it is common to require workers to execute some type of gowning validation, using touch plates or swabs, before they are allowed to work in the controlled environment. An understanding of the types of clean garments that are appropriate for the specific activities and environment is important as well. This can affect cost and operator performance as well as environmental bioburden.

Housekeeping. There should also be written and posted housekeeping procedures and training documentation. Close attention should be paid to cleaning materials such as mop heads and disinfectants as well as the frequency of cleaning and documentation of cleaning activities. For example, a strong disinfectant can destroy the integrity of a nonporous surface. Mop heads and wipes must not shed or leave

particulate. In addition, these cleaning materials must have use and rotation limits.

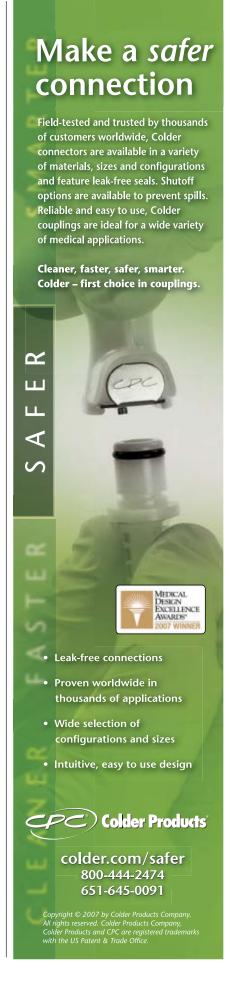
#### Conclusion

Unfortunately, there is not yet a single reference document for manufacturers to rely upon to design, validate, and demonstrate environmental testing compliance. ISO 14644 and ISO 14698 documents have eased the task significantly and are good resources for manufacturers of terminally sterilized products. The key is to keep bioburden in mind at all times. Step back and look at the manufacturing process, personnel, and environment as a whole when drafting a sterilization validation program.

The path to a solid understanding of bioburden starts with defining traffic patterns and identifying and limiting product and personnel contact areas. Characterizing, controlling, and understanding environmental bioburden levels and trends are the cornerstones of defining and implementing a solid environmental monitoring program that fully supports sterilization validation and release activities.

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# E-Labeling: A Global Reality

Developments in device regulations and technology have thrust electronic labeling into the spotlight.

Kristen Giovanis

he topic of electronic labeling (elabeling) appeared on many conference agendas and in a variety of journals throughout 2006. Yet, from a regulatory standpoint, the year was one of discussion but little action. A world of difference exists between a directive that specifies that labeling must "accompany" a device and a directive that specifies that labeling must "be provided." Such distinctions were the focus of last year's discussions, creating an opportunity for EU regulatory and legislative bodies to clarify e-labeling standards, as well as explore the technological possibilities that e-labeling presents.

When original labeling regulations were written, information technology (IT) was in its infancy. With advances in technology and the increasing sophistication of users, the shift toward paperless labels has gained momentum. Now the medical device industry is poised to bring together technology, regulatory approval, and customer acceptance to make e-labeling a viable, cost-effective, and care-effective option.

It's time for medical device companies seeking to maximize their global position, particularly in the U.S. and European markets, to understand the business advantages and pitfalls of adopting an e-labeling system. Although there are inherent risks in the transition, the potential rewards, for both patient care and profit, are significant. Companies must carefully weigh the benefits before going forward.

Kristen Giovanis is managing director of KJ International Resources Ltd. (Minneapolis).

#### **Regulatory Primer**

The December 2005 revisions to the EU Medical Devices Directive (MDD) further opened the door to electronic formats for product labeling, moving beyond the "leaflet" requirement specified in the previous version of the MDD. Also in 2005, the list of languages required for product labeling of EU-marketed devices was expanded to 20 languages. E-labeling allows manufacturers to

- Comply with regulations regarding reduced packaging and waste.
- Provide more-detailed information on a label, as well as different kinds of information (such as product demos).
- Speed time-to-market for new products and labeling updates.

But the revised language has also been problematic. The European Medical Technology Industry Association (EUCOMED), the primary European lobbying group within the medical device sector, believes that one complication comes from sections of the proposed revisions that would require labeling to "accompany" a product. In the era of elabeling, labeling can move beyond the traditional boundaries of printing and packaging to encompass anything from a CD-ROM to complex software to Web-based seminars for access-on-demand. To require that such new formats accompany a product restricts the ability of manufacturers to better serve caregivers and patients by providing more content-rich labeling at a lower cost.

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EUCOMED has proposed—and initial reports indicate that the European Parliament will approve—revised language to the effect that labeling must "be provided." Although this language would be vague, the revised requirement would enable manufacturers to take advantage of new technology and increasing user willingness to embrace elabeling for certain kinds of products.

In fact, user adoption will be one of the highest hurdles to clear in successfully introducing e-labeling. The few published studies to review user acceptance of e-labeling are hardly unanimous in their conclusions regarding its acceptability. Although a majority of users (mostly physicians) indicate that they are at least willing to try e-labeling in some situations and with some products, some users remain intransigent.

A Medtronic pilot study in 2004 surveyed 637 physicians in 11 EU countries and found that 35% preferred CD-ROM manuals for implants; 28% regarded CD-ROM manuals as equivalent; and only 4% of respondents would not accept a CD-ROM. On the other hand, a study conducted by the German Federal Institute for Drugs and Medical Devices (BfArM) in March 2004 concluded that the majority of users would prefer paper-based instructions for use and regarded an electronic version as a supplement to, rather than

#### **COUNTERINDICATIONS TO USE**

Not every product or market is appropriate for elabeling. To protect itself in the face of risk, a manufacturer must evaluate each product that is a candidate for elabeling and each market in which that product will be sold.

Oftentimes the question isn't whether the technology can create the labeling—the answer is usually yes. Users must have appropriate technology and infrastructure to support the format. Support requirements might include

- Access to and understanding of software packages, such as those that enable the reading of PDF documents.
- Reliable, secure Internet access.
- Access to computer equipment with sufficient memory to open and review large, content-rich files.
- Printing capabilities that ensure that materials reach locations where computers or Internet connections are not available.
- Ability to contact and use technical support, via phone, e-mail, or other real-time methods.
- On-demand print capabilities to provide paper-based labeling for customers who request it.

These requirements, which are a given in advanced markets, may make e-labeling untenable in developing markets. After all, if the labeling isn't accessible, viewable, sharable, or explicable, it cannot fulfill its purpose of making products safer and easier to use.

a replacement of, traditional formats.

Since 2004, companies have not gone public with the results of more recent studies. Anecdotal evidence suggests that the major manufacturers continue to slowly gauge user perspectives and requirements vis-à-vis e-labeling, and more controlled data will likely be released when regulations are finalized.

#### The Labeling Challenge

It's important to note that e-labeling does not come without challenges, albeit a different set of challenges than paper-based labeling. Regulatory bodies, product users, and manufacturers share the responsibility of addressing these challenges without compromising patient safety. Critics of e-labeling contend that

- E-labeling shifts the onus from the manufacturer to the user, who must retrieve labeling information (run a CD-ROM, go to a secure Web site, etc.) rather than read a leaflet that is contained in the package.
- Web-based labeling may not be secure, always accessible, or easy to reference in healthcare situations.
- User training may need to include how to use the elabeling system as well as how to use the device.

#### **Gaining Ground in the United States**

Still, the EU can look to the U.S. regulatory community's experience for reassurance that e-labeling does not compromise patient safety and that it improves a user's experience with products. The Medical Device User Fee and Modernization Act, signed into law in the United States in October 2002, explicitly permits e-labeling for prescriptive devices (as defined in the amended Section 502(f) of the Federal Food, Drug, and Cosmetic Act) used in healthcare facilities.

Users may request—and must be provided with—paper-based labeling if they prefer. Manufacturers submit elabeling to FDA during the approval process. Companies have provided labeling on CD-ROM, via secure Web sites, and through other media.

#### **Pharmaceutical Parallels**

Medical device manufacturers might well look to the pharmaceutical industry for clues to the future. FDA has already begun requiring electronic submissions in the form of structured product labeling (SPL) for regulatory approval. The transition is well under way in the EU as well.

The electronic submission requirement is predicated on the need to standardize data submissions in ways that are accessible and searchable. At the same time, electronic submissions have enabled FDA and pharmaceutical companies to streamline the approval process, speed time to market, and improve patient care standards.

By combining electronic submissions on the front end with e-labeling on the back end of the regulatory approval process, companies are able to reduce the human errors that can easily be introduced along the way. Reduced costs, shorter approval times, and improved safety are the main benefits.

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## **Examining the Technology**

While the regulatory world turns at a rate that can make geology seem like a thrill ride, technology evolves almost as quickly as one can blink. Companies ready to move toward technologically enhanced labeling mechanisms are already discovering capabilities that were not available just three years ago. With smart planning and timely technology deployment, manufacturers can position themselves to pounce as soon as more markets open up to e-labeling.

In addition to the user benefits of e-labeling, manufacturers achieve enormous benefit from the underlying e-labeling translation and production technology. For example, FDA's SPL electronic submissions requirements are based on extensible markup language (XML) technology. Companies using XML can share information easily with partners, suppliers, and customers, in addition to FDA. Clinical researchers and practitioners can communicate more closely through shared XML data, and even translators and other service vendors can gain faster access to the most up-to-date information to move projects (such as

updates) along more quickly. XML technology can help manufacturers lower costs as well as shorten project cycles.

Other kinds of technology also form a natural fit with e-labeling. More and more manufacturers are looking to manage their massive data resources through content management systems (CMS) and enterprise management systems (EMS). Whether relying on proprietary systems

or the ever-growing options for off-the-shelf applications, manufacturers using robust CMS and EMS systems can have single-source control over everything from print manuals to PDFs, Web content, and CD-ROM files and training curricula.

These systems ensure that users—both internal and external—always have the most current and accurate information. New publications, translations, updates, and releases can be managed through a central administrative system, and multiple outputs (paper-based, electronic, or a combination) can be generated off the same source materials.

Although proper implementation of a CMS or EMS requires strategic planning and resource allocation, companies that use these systems will find themselves ready to embrace e-labeling as well as traditional labeling, depending on the needs of their users and markets.

### Staving Ahead of the Curve

Step by step, regulations worldwide are moving toward implicitly or explicitly allowing e-labeling. Companies that wait too long might find themselves left behind the adoption curve. Manufacturers can stay ahead by employing several strategies.

Feasibility Review—Legacy Products. For each product already in the marketplace, carefully consider the pros and cons of moving toward e-labeling. Some products may perform best with traditional labeling, and others may be suited for e-labeling in specific circumstances, such as professional use. Also consider your update schedule for legacy products. When the labeling is updated, does it make sense to provide an e-labeling version?

Feasibility Review—New Products. For each product in the pipeline, do a similar cost-benefit analysis of implementing e-labeling. Pay particular attention to the number of markets, languages, and user types to come into contact with the product. Also consider your expected number of labeling updates. Products with few updates may be managed best with traditional labeling; products with multiple updates in several languages may benefit from e-labeling.

User Feedback. Regardless of current e-labeling implementation plans, start a dialogue with customers and users concerning their attitudes about and expectations of e-labeling. Try to find out how much potential users know

about it, how comfortable they are using electronic labels, and their technical capabilities for accessing elabeling information.

Technology Updates. Few companies have truly up-to-date technology capabilities for CMS and EMS. Take time to conduct a thorough information management audit to learn what your firm's information assets are and how close the company is to maximizing their use.

Identify any gaps in IT capabilities and develop a strategic plan for technological evolution that takes into account regulatory requirements, labeling needs, translation, and data access.

Regulatory Activity. The EU is expected to publish the final draft in the Official Journal by the end of 2007. When it does, expect a flurry of new activity as companies that have been waiting to act make their strategically planned moves. As these firms tip their hands, the next few years should be fascinating for industry observers as well as the players.

## Conclusion

Step by step, regulations worldwide

Companies that wait too long might find

themselves left behind the adoption

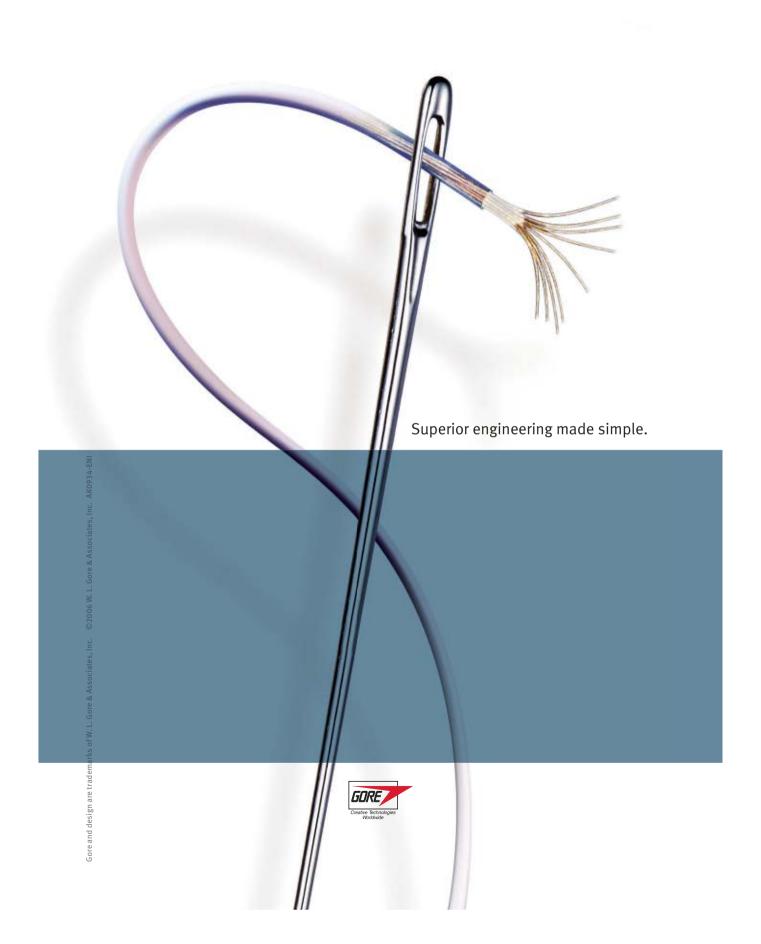
by employing several strategies.

curve. Manufacturers can stay ahead

are moving toward implicitly or

explicitly allowing e-labeling.

Although e-labeling presents a variety of opportunities for medical device manufacturers, it's important not to underestimate the complexity and depth of an e-labeling initiative. The biggest challenges rarely arise in the technological sphere. There are often underlying problems with business processes that must be addressed before an e-labeling project can move forward. By taking a collaborative approach that cuts across company divisions and includes service partners, technology, and regulatory groups, manufacturers can successfully plan, implement, and measure the benefits of e-labeling on global markets.



# Materials: Adding Sustainability to Product Development

Material selection can be an integral part of ensuring sustainability for medical devices.

Glenda Eilo

successful medical product undergoes a significant development cycle during which an OEM takes a concept and design, pairs it with a high-performing material, and produces a device within a reliable, efficient process to secure product integrity. In addition, progressive companies look at the total product life cycle and establish sustainability strategies. Integrating sustainability into the product life cycle requires consideration of the economy, protection for the environment, and social responsibility.

For the medical device industry, building in sustainability means reducing the amount of material or energy used, decreasing waste, and minimizing air emissions. It is more important than ever, therefore, for OEMs to carefully consider the materials that will go into their product. This article looks at materials selection as an integral part of the total product life cycle and the move toward sustainability.

## Conceptualizing a Medical Need

Medical devices must generally meet a need, but manufacturers also want to create a functional design that factors in human interaction and is aesthetically pleasing. In doing so, manufacturers must also address market challenges and trends. These trends include the shift of healthcare away from hospitals, the nursing shortage, and the aging population. Trends such as limited product reuse—a medical device that is either disposable or has very limited

Glenda Eilo is global industry leader, medical plastics, for Eastman Chemical Co. (Kingsport, TN).

Cannulae used for arthroscopic or minimally invasive joint surgery are tinted so that surgeons can distinguish between different cannulae during surgery.

usage—must be considered during initial concept development. Limited product reuse may need to be considered as a way to mitigate the spread of infectious diseases as well. For instance, there are plastic medical devices that cannot be sterilized more than once, making the device a one-time use product. During concept development, it is important to understand the plastic resins available that can ultimately enhance a product's effectiveness. Understanding resin options ensures that the material selected is appropriate for the product's care settings as well as its manufacturing and sterilization processes.

For example, it is important to review available materials in the earliest stages of developing a device, such as a sleep apnea mask for an aging population. As more and more seniors are diagnosed with sleep disorders, treatment has moved from a hospital-only environment to include home treatment. Although a sleep mask would be used in both treatment settings, the one manufactured for the hospital might be a single-use disposable, whereas a reusable version could be manufactured for use in the home.

OEMs must make sure that products are created to suit each environment, and so firms must examine manufacturing processes, distribution, use, and disposal. In the example



My client was facing multiple printing dilemmas. I gave him all the time he needed.

- Julian Joffe, President

Joe Santana, President of Timex and I have known each other for quite some time — he gives me a watch every year for my birthday. When Timex needed a cost-effective way to print watch faces and bezels, we listened and devoted all the time needed to deliver custom solutions. Over the years, we've worked together on multiple projects and concepts. Joe knows we take the time to deliver the precise solution, on schedule, every time.



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mentioned above, then, it is important to know that a more cost-effective polystyrene would be appropriate for the hospital mask whereas a high-performing engineering polymer would best suit the home environment. Material selection is just one decision in the process; however, it demonstrates how concept and design can be translated into a customized medical device that serves the same patient need in two different environments.

## **Designing for Human Interaction**

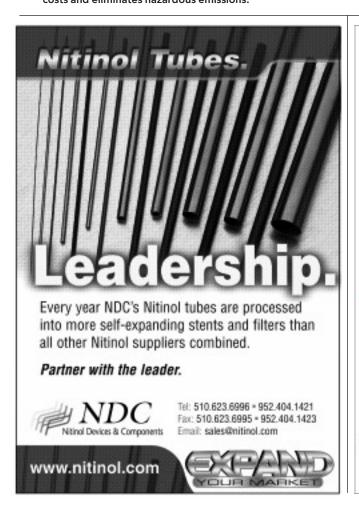
Effective design takes into account the patient's emotional response and thereby improves the patient experience. In the past decade, material selection was often left up to an engineer responsible for the product manufacturing process, often too late to make adjustments that might yield more-efficient production or better product functionality. The need to innovate and differentiate, however, has changed the landscape for medical product companies; today's medical products need to

This IV bag is made from a PVC alternative that is clear, resilient, and autoclavable. The material also reduces medical waste costs and eliminates hazardous emissions. be more user-friendly to help address problems such as worker training and language barriers, as well as to suit the environment in which the device will be used. OEMs must connect material performance to market need and must identify an appropriate mold method, the optimal sterilization method,

and the right regulatory path. Designers need to understand a material's properties as well as its performance attributes and how a given material could be used to address patient issues and market trends.

## Optimizing Material Selection

Material selection is driven by performance potential and ease of processing. Now, more than ever, it is also driven by sustainability (see the sidebar, "Creating Sustainability"). With a broad range of medicalgrade resins available, there are greater possibilities for medical OEMs to choose from. OEMs must apply the right material to a device or packaging design to enhance human interaction





### **CREATING SUSTAINABILITY**

The growing desire to embrace sustainability challenges OEMs, suppliers, and other players to join together in the effort to continue to deliver exceptional healthcare products that have minimal effects on the earth.

As a result, more and more product development strategies are being built around optimization of manufacturing, recycling, or disposal to minimize environmental effects. Trends such as device miniaturization and the concern for producing less vaporous emissions are on the rise.

OEMs are relying on the plastics industry as a resource to learn more about alternative materials, design parts with less material, and streamline manufacturing to save energy. To this end, the industry is responding with ongoing research of biodegradable and recyclable plastics, and improving processing methods to help create industry solutions that benefit the planet.

while reducing the development cycle and minimizing scrap or production interruptions.

Test data help confirm the attributes necessary to deliver the appropriate level of design flexibility, strength, clarity, and chemical resistance—key attributes for devices and packages with maximum integrity. Comparing data makes material selection simpler. Material properties are also matched to application performance, secondary operations, and regulatory guidelines. And in the case of a product redesign that leads to material conversion, companies should seek out materials compatible with their existing sterilization and validation processes to contain costs and expedite processing. For instance, frequent breakage prompted a provider of natural collagen vascular grafts to convert its glass culture tube to a stronger, more resilient package.

The grafts are used for hemodialysis grafts and peripheral bypasses, so it was important for the company to select a medical-grade copolyester to ensure











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cessfully after ethylene oxide (EtO) and gamma sterilization. In the end, the package was robust, stable, and safe without compromising surgical readiness or performance of the grafts. The new material also decreased secondary packaging and lowered costs for transport and warehousing.

## **Achieving Effective Production**

Efficient manufacturing requires optimization of part design, mold design, and processing parameters. Having a comprehensive production strategy in place becomes an OEM's insurance against costly production mistakes. Moreover, efficient processing coupled with good quality control can decrease energy use, minimize waste, and improve sustainability.

OEMs must indicate to their supplier early on whether a medical product is to be injection molded, thermoformed, or extruded, and whether there are multiple parts that must be factored into the design. For example, a specialized medical plastics team might review the initial part design for uniform wall thickness to improve part strength and joint design and to maximize product performance.

An OEM would also benefit from a tooling review that analyzes mold design features such as the type of feed system (hot or cold runner), gate design (hot or cold gates), cooling line arrangement, venting, and ejection system to correctly match the material to the process. As part of this process, a mold simulation would pinpoint gate location, the fill pattern, and fill pressure of the proposed

To ensure bond integrity and viable device operation of a multiple-component part, OEMs need to understand how to choose a part-joining method that best suits the selected material. Bonding options include adhesive bonding, solvent bonding, welding (ultrasonic, laser, hot plate, vibration, etc.), mechanical fastening, snap fit, press fit, and cold forming. For example, solvent bonding could be used on flexible copolyester tubing to minimize crazing, stress cracks, and bond failure. To join two clear parts, laser welding might be suggested.

## **Sterilizing for Product Integrity**

Medical products must not be compromised after sterilization. Key to achieving this goal is matching the resin to a cost-effective sterilization process that reduces bioburdens without negative effects such as a color shift or physical degradation. Medical-grade polymers used for devices such as syringes, tubing, pump housings, caps, and dialysis components are typically sterilized via EtO, gamma radiation, autoclave, low-temperature hydrogen peroxide gas plasma, or electron beam (E-beam). Most high-volume medical products are sterilized via gamma or EtO, the latter being more expensive and requiring a time-consuming quarantine.

Recent improvements in efficiency have increased the popularity of E-beam sterilization, making it a safe, reliable source of energy that is gaining popularity due to its lower cost. Additionally, E-beam sterilization can be conducted in-house during the packaging process. It is not regulated like gamma radiation because radioactivity is not Companies choosing E-beam sterilization for their transparent medical devices should be aware of the potential for color shift after sterilization. Thorough testing data are a good indicator of how the physical and optical material properties of a particular polymer are maintained after certain sterilization processes.

## Packaging for Distribution and Use

Whether a company is looking for rigid or flexible packaging, the material must provide a microbial barrier and lasting protection throughout the supply chain and during

storage—product must retain



Available technical data helped a surgical instrument maker reverse engineer a package design that resulted in a 16% reduction in material costs and a 15% increase in manufacturing capacity.

its integrity and fitness for use. OEMs need to take a holistic approach to a package's distribution and use. It is important to choose packaging that provides the necessary physical, thermal, and optical performance. Important material attributes for packaging run the gamut from clarity and good melt strength to ease of thermoforming and the ability to be sterilization stable. To adequately meet these performance demands, it is essential for OEMs to tap into available technical data to efficiently produce packaging that diminishes medical waste and environmental impact. Such data are readily available on supplier Web sites.

For example, when a large medical company was looking to create a durable, flexible IV container that was also environmentally friendly, it chose an elastomer as an alternative to PVC. As a result, the company

minimized a secondary overwrap while reducing punctures and decreasing medical-waste costs and hazardous air pollutants.

For another company, material data helped them consolidate five current package designs into one. The new robust design reduced material costs by 16%, increased manufacturing capacity by 15%, and created a package that was 25% smaller, providing additional shipping and storage savings.

### Conclusion

Understanding materials can help OEMs optimize each stage of the product development cycle and deliver safe, easy-to-use product that poses the least environmental risk. Reviewing performance data enables companies to develop sound, effective medical products and packaging.



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## Improving Logistics and Inventory Control

Medical device firms may benefit from using logistics vendors. Here are some tips on selecting the right third-party provider.

Len Batcha

t is common for medical device manufacturers to outsource the transportation and delivery of their devices to customers. This means that shippers tender their goods to carriers (i.e., truck lines) to perform the transportation of goods from origin to destination. The shipper selects the carrier it wants to use, but the carrier is responsible for routing, equipment, and scheduling.

The use of third-party logistics is not new, but service providers can now offer much more than truck lines getting the product from point A to point B. Services specific to the needs of medical device OEMs can include warehousing and inventory control, transportation, delivery, assembly, installation, and repair of equipment in the field.

The internal strengths of a medical device manufacturer are often rooted in product development and manufacturing, rather than in shipping or warehousing. Therefore, third-party providers can give OEMs the means to access existing equipment and material-handling services. They can also provide established inventory control, systems applications, and on-hand trained personnel.

If a medical device manufacturer elects to employ outsourcing services, the manufacturer is responsible for ap-

Len Batcha is president of Technical Transportation Inc. (Southlake, TX).



Moving and shipping medical devices, such as this infant incubator, requires skills and equipment that are often beyond a manufacturer's capabilities. A third-party logistics provider may have the necessary expertise.

proving the third-party provider as a vendor. To become an approved vendor the provider must have an established quality program in place. The vendor is subject to compliance and is liable for quality facets required by the manufacturer.

These compliance factors, which are established by ISO guidelines and FDA regulations, are generally defined and audited by the manufacturer's internal regulatory department. Compliance

factors include, but are not limited to, device history tracking (i.e., documentation and database control of inventory transactions related to receipts), cycle counts, picking, and distribution and transportation. Additional factors include delivery of devices by date, quantity, serial or lot number, consignee or facility name, and signature acceptance. For repair services, the date, time, and nature of the repair must also be recorded and included as



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part of the device tracking history. When customers demand improved services in these areas, device manufacturers find that they must also become experts in logistics.

It is important to evaluate whether a manufacturer can handle these functions in-house. A manufacturer's ability to track, ship, and service equipment efficiently can often be a competitive advantage. Such functions, however, require time, resources, facilities, and capital investment. This article provides an overview of the types of logistics services that manufacturers may prefer to outsource.

## **Warehousing Site Selection**

An advantage of employing a logistics provider is its knowledge and experience in selecting warehousing sites. However, when logistics providers select a warehousing site, the process should remain driven by the device manufacturer. This means that when considering an option, it should be customized to fit the client's needs. The options should be built around the client rather than trying to fit the OEM into existing processes.

Criteria regarding warehousing are determined by the needs and objectives of the manufacturer. Factors that need to be considered when selecting a facility are numerous and should be defined prior to initial search.

One significant factor is facility size. The site's square footage must be sufficient to accommodate peak inventory levels. In addition, the level of security at the site should be high. Monitoring systems are a must, as are alarm systems. Fire protection and sprinkler systems should be rated in compliance with current insurance requirements. Older facilities that do not have upgraded sprinkler systems may not be rated to protect devices packaged in corrugated, wooden, or plastic cases.

Dock accessibility is another factor that must be taken into account. The facility must have a sufficient number of doors, including levelers and secured access, to accommodate the expected traffic volume and required equipment (trailers, bobtails, containers, parcel ramps, etc.). Another important consideration is the storage tools and han-

dling equipment that are on-site to accommodate unloading, stocking, picking, and packaging (if necessary) of the medical devices. Determining whether the devices are stackable may also play into the storage techniques and processes. Some devices may be fast sellers and it makes sense to keep the floor loaded and organized for efficient product flow.

Whether the facility is in a free-trade zone (an area of a country that has limited taxes or tariffs to attract business and investments) might become a factor if medical devices are imported from other countries. If a facility is in a designated free-trade zone, the device shipper may benefit by avoiding

A manufacturer's ability to track, ship, and service equipment efficiently can be a competitive advantage.

import or customs tariffs if devices are released within designated time frames.

Device manufacturers may require environmental conditions that accommodate a certain temperature or humidity range. The facility must have heating and air-conditioning units to regulate both temperature and humidity. Systems applications should monitor and record these readings within the facility at all times. Protocols for measuring and monitoring must be defined by the device manufacturer, and compliance measured by output of the monitoring devices.

Most sites offer exclusive-use vehicles or dedicated trucks and drivers to perform delivery functions. During the process of site selection, make sure that all vehicles are well maintained. It's also critical to ensure that they have pallet jacks and proper equipment to transport materials, and are compliant with federal regulations. Drivers also must meet certification or training standards. Such detailed checks are routine for third-party logistics providers, which is helpful to manufacturers because many do not have

the time to ensure these factors are in place.

Many logistics providers have an existing database of warehouse partners to help narrow the selection of suitable warehousing sites. If no match can be found, the logistics company can find a new warehousing site.

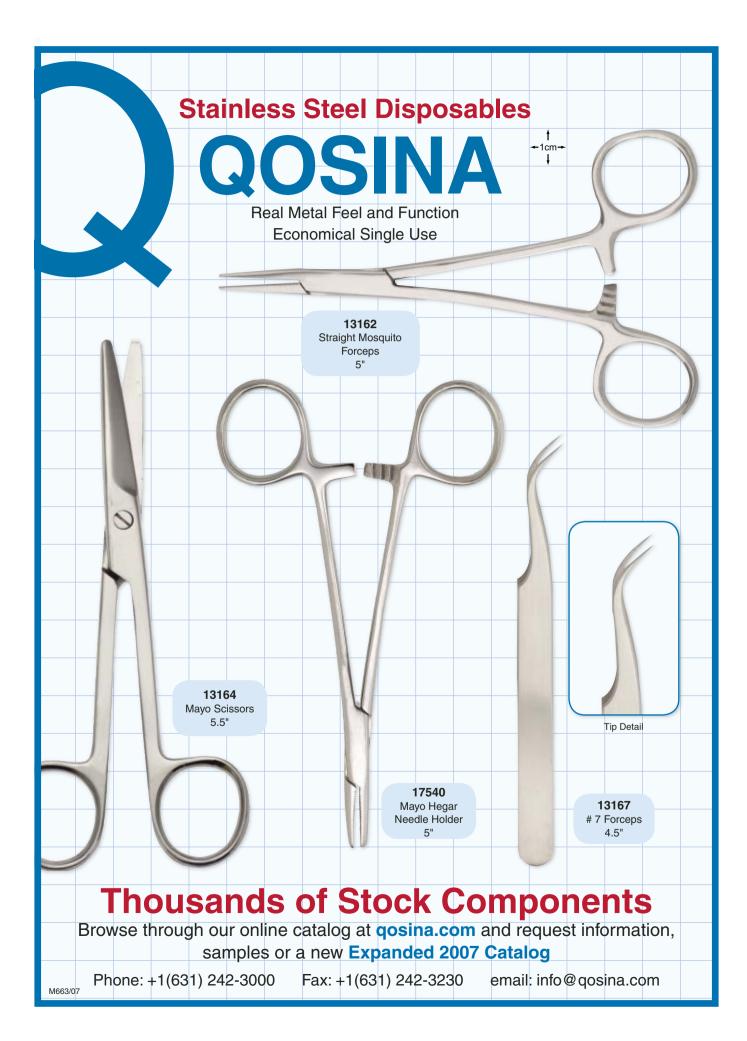
If it is determined that the manufacturer's needs are best suited by a warehousing site not previously used by the logistics provider, the manufacturer can conduct initial interviews over the phone. If the site appears to be a match, a member of the project team within the third-party logistics provider should visit the site. Selecting the site is based not only on fulfilling the requirements of the OEM, but also on specific criteria already established by the third-party logistics provider. It is the logistics firm's reputation and overall obligations to the manufacturer that are at stake. Criteria may include visibility, location, safety measures, professional environment, and whether the device manufacturer's sales representatives are comfortable with the site. A clean, organized, and professional environment with a pleasing look suggests to the sales representatives that their product is well cared for and provides for the possibility of potential customer visitations or demonstrations on-site

The final approval of a new site is granted by both the third-party logistics provider and the manufacturing company after ensuring that it meets all checklist standards. The manufacturer saves time by relying on the logistics provider to find the most appropriate site, but it should still have final approval rights.

## **Inventory Control**

Inventory control is the practice of minimizing the total inventory costs, which is a key concern for medical device manufacturing. It plays a role in quality systems management for meeting regulatory requirements. The basic factors in inventory control and processes include the following:

- The carrying cost of the material (with the current interest rate considered).
- The cost of placing an order,



including the setup cost of production.

• The cost of shortage (the economic loss if the stock is insufficient to meet the demands).

The last factor is the most difficult to measure and is often handled by establishing a service-level agreement, for achieving effective inventory management. For example, the medical device unit or system is usually considered an A item. The unit itself is usually defined as *high value* based on assembly and as dictated by the sales price. Loss or damage of a device results in a significant dollar write-off or potential loss of sale. Accessory

## **KEY PERFORMANCE INDICATORS**

Logistics providers should offer secured system applications that can be seamlessly integrated to manage inventory control and resource planning. Examples of such applications are Oracle, SAP, and Microsoft products with support-system applications. Choosing a logistics provider can be simplified by looking for key performance indicators. Common indicators include the following:

- Receiving dock-to-stock cycle times is measured in hours rather than days.
- Order processing is measured in order of completion with or without back orders.
- Processing occurs within defined cutoff parameters, and product is tendered for transportation on the same day.
- Inventory accuracy is measured via cycle count or physical wall-towall inventories as defined by the manufacturer.
- Data exchange should be in real

time or file transfer.

- Defined requirements for delivery is measured by actual receipt of shipment instead of by the estimated time of arrival.
- The damage-free report is measured by number of units in shipments processed.

A logistics provider should be able to deliver 90% of receipts to stock within an eight-hour work window. With regard to order processing, a specific plan should be in place, such as shipping of 99% of receipts on the same day with a defined cutoff time of 2 P.M. for normal shipments and 4 P.M. for emergency order downloads. Orders after these cutoff times are subject to transportation carrier cutoffs and usually fall into the next day's business. Indicators also include inventory and cycle count accuracy of 98% of receipts and order delivery of 98% of receipts that were on time (meaning within a 15-minute window of the defined date and time).

meaning that an established percentage of demand will be met from stock without delay or shortages. Established inventory control practices and applications support improved control. Inventory control is a required expertise of a logistics company.

Inventory ABCs. Many manufacturers and third-party logistics providers operate under an ABC classification system. The ABC system is a method of grouping items according to annual sales volume, cost of product, or lead time for production to identify the small number of items that will account for most of the sales volume. These products are the most important

items (such as monitors, printers, or other add-on assemblies) that are not as critical and can be easily sourced or interchanged because they carry a lower dollar exposure are considered B-type items. Consumables such as paper, gel, and other disposable-type items carry a lower exposure from a dollar and replacement value and are usually considered C items. Long-lead-time items, although they carry a lower dollar value, are often considered an A or B item because back orders can affect sales.

Product dimensions and weight need to be factored in for proper handling and storage. OEMs should also consider whether the material or product should be tracked by identification and description, by a serial number or lot control tracking bar code, or by a radio-frequency device. Automated tracking applications can improve accuracy by validating storage locations, item identification (by serial, lot, or radio frequency), cycle counting and picking, and order consolidation before shipping. By scanning locations and item labels controlled by scanning devices at each process, immediate verification is recorded and tracked by the system application. The system application stores these transactions in a database and is immediately accessible for cases in which potential regulatory recall may be required or inventory adjustments for investigation and validation are employed.

Regarding the inventory itself, any specific storage requirements such as temperature, climate control, and security must be addressed along with the quantity and packaging integrity of the product. The third-party logistics provider can then address any issues with facility requirements, such as the square footage required for storage and any special requirements for racking or storage equipment. In terms of setting up inventory control, the logistics provider must be told the historical activity by product and any forecast information related to shipment activity for the product.

Safety Stock. A logistics provider should be able to control the product. Its job is not only to make sure that the space is adequate and to validate transactions on receipts and distribution, but it also must prepare for unexpected events by emphasizing the importance of safety or buffer stock. Safety stock includes inventory remaining after an order is placed and before new stock is received. If there is insufficient product inventory, shortages can occur. Safety stock is a hedge to take care of unexpected events. Safety stock must be tracked and accounted for in terms of ensuring that the warehouse has enough space. System applications that control defined-lot product are managed by entering the expiration date into the system at time of receipt. The parameters that automatically place a product lot on hold or

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in quarantine are defined within the application by product. The system will not allow allocation and disbursement of an expired product by the application unless it is overridden by a product specialist with proper security access. Typically, expired product is placed in quarantine 30, 60, or 90 days before the actual expiration date.

Inventory Tracking. Once the warehousing site has been selected and inventory is moved in, it is time to deliver the product lots to the correct locations. Inventory tracking takes into account any delivery notification requirements expected from the OEM. It also determines whether any specific communications (such as proof of delivery) with the shipper or manufacturer are needed. A logistics company should be notified when signature by the consignee and proof of delivery are

recorded. These should be made available to the device manufacturer for immediate revenue credit. Proof of delivery can come via automated e-mail notification, a Web site report, fax copy, or even phone verification, as the manufacturer prefers.

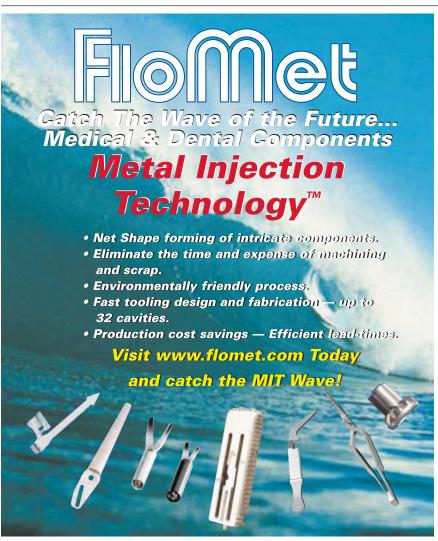
Application databases hold all transaction history and must be accessible and available upon request by the OEM. The logistics provider should have information available instantly online or within minutes to e-mail or download it via file transfer protocol. Keep in mind that downloads may only be available during normal business hours. Online information does not have such time restrictions but the shipper should require security codes to access data.

The inventory control application should be able to manage national holds on specific lot numbers as needed. Time is a significant variable when managing a national hold or a recall. The sooner information is available. the sooner a device manufacturer can invoice, react to inventory demand, and react to potential recalls. Quick delivery of such information means that the OEM can minimize its recall or hold costs.

## **Transportation and Delivery**

It is up to the third-party logistics provider to determine the transportation requirements of the manufacturer for safe and effective delivery of the product. To determine these requirements, the provider may analyze the breakdown of historical information and the number of shipments required for same-day, second-day, and threeto-five-day processing and delivery.

Delivery requirements vary based on each specific commodity. Logistics providers should ask the manufacturer to help define those delivery requirements for its products. There are certain commodities that require inside delivery to a specific area for unpacking, general setup, and some assembly with debris removal, while other commodities may just require a dock signoff delivery. Whatever the needs might be, logistics providers should match their service requirements to accommodate the prescribed transportation mode and commodity



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delivery requirements.

For example, a medical device that weighs more than 1000 lb may need to be delivered to a specific room or floor within a facility. Such an instrument would require at least a fourperson delivery crew to properly offload the device and manipulate it through a receiving dock or parking lot (consider offices or labs in a plaza or small clinic). The delivery crew must protect the facility's floors and interior from damage caused by a heavy device or the material-handling equipment required to move the device through the facility. Such equipment might include a crawler for stairs if a freight elevator

Application databases hold all transaction history and must be accessible and available upon request by the OEM.

is not available, or a forklift or pallet jacks to move the device through halls. The delivery crew also needs to bring the necessary tools to uncrate or unpack the device and to place the device in a specific location or lift it onto a table or other item.

Medical devices must be tracked using device history folders. The serial number with consignee signature should be documented and given to the manufacturer to include with the device history package.

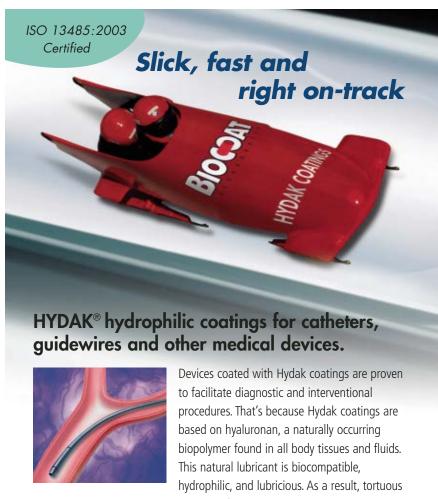
## **Reverse Logistics**

Picking up should be as simple for the logistics provider as dropping off. A comprehensive reverse logistics program offered by third-party logistics providers typically includes some or all of a set of several tasks. These tasks include repacking in appropriate crates that offer maximum protection for the product, equipment removal from the end-user site, equipment pickup, and disposal or destruction of items that are no longer of value (these are often destroyed in the field to avoid return transportation costs). Proof of destruction in the field must be recorded on approved documents and provided to the manufacturer for inclusion in the device history record.

Returns should also be recorded through the system application, as should the address, signature of the returning facility, and the return location and signature.

Upon completion of delivery, thirdparty logistics providers can bring the packing materials back to the warehouse and save them until needed at no charge. Instructions on how to properly pack each specific instrument would be included in the pickup alert. Instructions for unpacking are usually only defined for devices.

All of these tasks can be tedious and time consuming; the manufacturer may want to hire a logistics provider to take responsibility for them. However, choosing an outsourcer requires a manufacturer to define its needs up front.



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## Selecting a Provider

Choosing a logistics provider is a multistep process. The manufacturer sends formal requests for information and requests for quotes. These documents provide the basic required information. The logistics provider does not necessarily have a script or formula to extract, but instead uses the data provided by an OEM to form a logistics plan.

The request for information (RFI) is usually submitted as a formal document (either on paper or via e-mail) to several potential logistics providers that offer services that seem to fit the basic requirements. On the RFI, the OEM lists its broad-based requirements with enough information to give the provider an idea of the general scope. The manufacturer should request references and contact information from other companies using the logistic provider's services. The RFI should also ask the logistics provider to define its existing processes in detail and to provide flowcharts detailing those processes.

The third-party logistics provider should describe options for problem-solving and proposed methods, along with quality programs and systems currently employed. General pricing to accommodate the services and detailed information regarding the firm's organizational structure and support groups should also be provided.

Once a short list of the candidates is selected, the manufacturer submits a formal request for quote (RFQ) to each. The RFQ is typically more detailed and describes actual volumes and product composition. Further detailed requirements are defined as a result of input from the RFI answers. Often a manufacturer requests that a formal presentation be made by each of the bidding companies to the selection committee.

After the formal answers to the RFQ are submitted and presentations are complete, the company can evaluate the options and make its selection based on any predetermined factors (e.g., cost is more critical than the actual geographical location, or quality is more important than cycle time for receipt or storage).

Once the third-party logistics

provider is selected, contract negotiations begin. The OEM and the logistics provider must agree on and document terms for length of contract, terms for payment, and terms for legal liabilities. There are usually service-level agreements attached to the contract, (e.g., third-party logistics providers will maintain 99% inventory accuracy, 98.5% orders shipped complete, 99.4% damage-free, receipt and storage within 24 hours; and orders processed within two hours). Once the timeline for implementation is defined

Manufacturers should evaluate their internal strengths and determine whether they can perform these tasks without enlisting outsourcing vendors.

and the contract is signed, the relationship between the client and the provider begins.

## **Assessing Outsourcing Services**

When considering whether to employ a third-party logistics provider, it is important to factor in the expenses and costs associated with them. Determine whether the costs of such services are a worthwhile investment.

Using a third-party logistics company requires an investment that is similar to keeping logistics in-house. And at times, costs related to labor and facilities are more than a manufacturer anticipates. But these costs are necessary expenses of doing business, whether in-house or with a third-party provider.

Third-party logistics providers have some advantages over in-house processes simply because the provider may have more experience. Their processes, facilities, system applications, personnel, and equipment are already in place. Most third-party logistics providers enter into term contracts with their customers that can range from as little as 12 months to five years. Moreover, the burdens of facilities investments and depreciation of as-

sets currently exist with logistics providers.

Third-party logistics providers are staffed with personnel that have been professionally trained and educated in business logistics. They can often develop unique customer reports and notifications that can be formatted to electronically notify customer and personnel applications securely.

Such reports provide specific information that includes shipment origin information, consignee information, shipment date, shipping status, serial and lot information if present, quantity, receipt date, consignee signature, and any related comments or exceptions related to the delivery. Other reports include inventory balance on hand, cycle count reports, inventory transaction activity reports broken down by receipts, and inventory adjustments. These reports can be provided by specific part number, range of part numbers, or the entire inventory. Additional reports also include shipment activity, labor resource activity, and product use reports.

If needed, there are logistics providers that operate an OEM's own software applications.

Some have also developed transportation routes that allow for sameday, next-day, or expedited ground services to meet customer needs. These can minimize costs by taking advantage of shipment volume that they offer over their entire customer base. Route management provides methodology to consolidate shipments destined for a specific metropolitan or regional geographic area. By consolidating shipments, the cost for shipping is spread across all of the shipments, thus reducing the overall cost of an individual shipment. For example, instead of sending an individual shipment via an expedited parcel carrier, shipments can be consolidated to travel via LTL (less than truckload) at a reduced cost and arrive within the same transit parameters. In addition, route management can report on shipment trends so that a manufacturer can effectively trend transportation cost and schedule and predict order releases.

Third-party logistics providers can present personnel assistance to deliver equipment inside the end-user's facility. They can unpack the equipment, assemble, and even perform a start-up of the equipment, or they can simply meet a field service engineer on-site at a predetermined time to assist with these processes. They can also create space for field service personnel to perform system maintenance and upgrades to avoid the costly expense of shipping a unit or several units back to a repair facility. Additionally, they can set up strategic stocking centers that allow a manufacturer to warehouse units or critical parts close to the customer to avoid costly downtime and additional transportation costs for shipping the product overnight.

Manufacturers should evaluate their internal strengths and determine whether they can perform these tasks without enlisting outsourcing vendors. Once the manufacturer decides to outsource, it should work with the logistics provider to define continuous improvement objectives to ensure that benefits can be recognized and cost

savings are shared. Such improvements can easily be achieved by evaluating the history of shipping products. For example, examine the number of expedited shipments versus products sent via normal transportation mode. Evaluate the reason expedites were required and then make a plan to reduce the need by building more inventory, implementing order placement cutoffs, and improving warehousing organization.

## Conclusion

As technology continues to evolve, it is only natural that the demands of customers increase. Device manufacturers have specific needs, and their selected logistics provider must be sensitive to those needs.

Manufacturers must also be aware of the changing demands of their customers. Some items are becoming more compact, and larger loads are expected to be moved. Not only are customers demanding expedited arrivals,

but they want it done more efficiently and effectively, with proof of performance or function. Third-party logistics providers can help navigate these changes so that manufacturers remain effective. Today, in-house fleets of trucks and drivers are often impractical due to the changing sizes of goods and the amounts that need to be sent. A third-party logistics provider can adjust to these changes without the OEM's assets depreciating or the company having to absorb costs. Third-party logistics providers simply adjust to the changing product needs.

Third-party logistics providers can offer services that are difficult and time-consuming for manufacturers to perform in-house. Examine the areas of strength, such as warehousing, inventory control, transportation, delivery, and reverse and repair logistics, that are offered through outsourcing to help make a selection. Employing third-party logistics enables an OEM to focus on its areas of expertise.



## Assessing Robot Performance for Device Manufacture

A properly selected and integrated robot can be a valuable asset for medical device manufacturers.

Bruce Fiala

medical device manufacturer with a robot that offers high-quality performance in terms of speed, precision, and durability possesses a valuable tool. Conversely, if a robot's use is based on misguided assumptions about its performance, or if it has not been properly integrated, it can be the biggest problem on the production floor.

When considering robotic automation of a task, it is imperative that medical product design and production engineers understand the fundamentals of robot operation. This article discusses these characteristics as well as a strategy for properly evaluating vendors and integrators of robots.

In medical device assembly, robots have often supplanted humans in repetitious, fatiguing tasks that require constant precision, flexibility, dexterity, and speed. There are a variety of applications in device manufacturing for which robots can be used. They include the following:

• Small-parts assembly (dexterity,

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Six-axis articulated robots perform chassis-to-base needle insertion and placement on an insulin delivery pump.

speed, and precision).

- Part transfer (speed and softwaredriven decision making).
- Part presentation (precision and speed).
- Dispensing (speed and precision path).
- Packaging (speed and flexibility).
- Multiple part types (flexibility and programmability).

## **Testing**

Although robots can be significant assets for medical OEMs, they can have serious limitations if improperly integrated. These limitations are not apparent in a robot's specification sheet, and vendors are often unlikely to inform OEMs about them.

Many device manufacturers do not have robotics expertise, and it may be to an OEM's benefit to form a partnership with a qualified, experienced robotics integrator. Unlike a robotics supplier, an integrator assumes the risk of a robot's performance in an application. Therefore, integrators must be impartial to a specific company's products and select the optimal robot for an application based on characteristics such as precision, settling time, and speed.

Table I lists four typical specifications for a four-axis selectively compliant assembly robot arm (SCARA). Tables II–IV list specifications for other six-axis articulated arms and demonstrate how each robot vendor presents repeatability differently. The SCARA specification notes each axis individually, but Robot #1 just lists a number, Robot #2 mentions an ISO test, and Robot #3 lists constant-temperature data. Each vendor supposedly collects a considerable amount of performance



data guided by a standard, but no real details are presented. The lack of a standardized presentation for robot performance data makes it virtually impossible to make a robot selection using specifications only.

Proper robotics selection may require performing an independent comparison testing of the robot candidates. Speed, precision, and settling-time tests must be performed with a thorough understanding of a given robot's characteristics and the application for which it will be used.

Two industry standards—ISO 9283 and ANSI/RIA R15.05—outline requirements for the performance testing of robots and data reporting methods. The two standards are significantly different in terms of test paths, terminology, and performance test specifications. In addition, some very important performance aspects—multidirectional performance testing,

FOUR-AXIS SCARA				
Reach	_	350 mm		
Payload	_	5.0 kg		
Joint Speeds	X/Y Z Theta	7000 mm/sec 700°/sec 2600°/sec		
Joint Range	9	±150° ±145° ±190 mm ±360°		
Repeatability	X/Y Z Theta	±0.014 mm ±0.011 mm ±0.005°		
Weight	_	21 kg		

Table I. Repeatability specifics and overall characteristics for a four-axis SCARA robot.

for example—are often vague, optional, or not considered in either standard.

Published specification data might also lack information to help OEMs determine which robot manufacturers test to a standard, and if they do, which standard they use and how closely they follow it. In addition, most suppliers do not reveal their internal testing results. This raises the following four key questions:

- Under what conditions are published data valid?
- What do the data mean?

- Is robot performance guaranteed to meet the published specifications?
- What important characteristic data are omitted and left to chance?

## **Understanding the Fundamentals**

Resolution, repeatability, backlash, and accuracy are the fundamental characteristics of robot precision. The following definitions are provided to help understand the significance of these characteristics.

*Resolution:* signifies the smallest directional amount an axis can move.

Positional repeatability: the maximum radius of a sphere containing all of the end points achieved when moving to the same location from the same direction numerous times.

*Backlash*: the magnitude of the motion lost between driving and driven elements due to clearance between parts.

Positional accuracy: the maximum radius of a sphere containing all of the end points achieved when moving to the same location from multiple directions, in different poses, and numerous times. (When testing to the ANSI/RIA standard, this is performed at many points in the work space looking for the maximum error.)

Resolution, repeatability, and backlash are solely based on mechanical systems, but accuracy builds upon the mechanics with mathematical relationships added to relate each axis to the robot's kinematic model. Repeatability and accuracy are represented in Figure 1.

Kinematics represents the static relationships needed to mathematically relate the robot's tool (flange) coordinate system to the real-world coordinate system. These relationships are in the form of lengths, offsets, and angular associations between serially linked axes (see Figure 2).

Mechanical inconsistencies and errors in these mathematical relationships are the major source of robot inaccuracies. The magnitude of inaccuracy increases when there are more degrees of freedom, the distance between axes grows, or rotary joints are featured rather than linear or fixed perpendicular joints (as found in SCARA robots). Errors compound nonlinearly as each axis is added to

the serial stack.

Due to manufacturing differences, no two robots can ever be characterized as the same. Major dissimilarities include casting differences such as length and twist, bearing fits within the castings, and gear-train nonlinearities. The physical relationship between the robot's flange and its base must be

SIX-AXIS ROBOT #1			
Reach	_	700 mm	
Payload	_	3.0 kg	
Motion Speed	Joint 1 Joint 2 Joint 3 Joint 4 Joint 5 Joint 6	180°/sec 180°/sec 220°/sec 410°/sec 325°/sec 720°/sec	
Joint Range	Joint 1 Joint 2 Joint 3 Joint 4 Joint 5 Joint 6	±320° ±180° ±315° ±380° ±240° ±720°	
Repeatability	_	±0.04 mm	

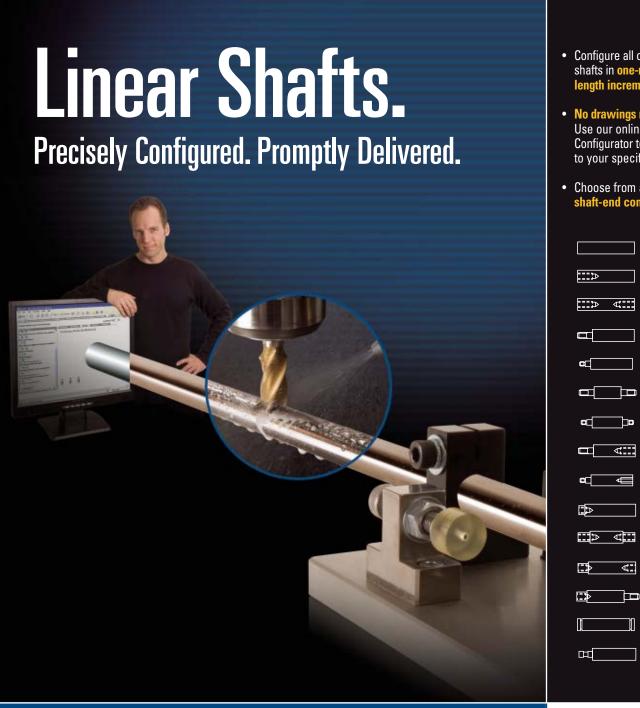
Table II. Repeatability specifics and overall characteristics for six-axis robot #1.

SIX-AXIS ROBOT #2			
Handling Capacity	5 kg		
Reach of 5th Axis	1.4 m		
Supplement Load on Axis 1 on Axis 3	18 kg 15 kg		
Position Repeatability	0.05 mm (average)		

Table III. Repeatability specifics and overall characteristics for six-axis robot #2.

SIX-AXIS ROBOT #3		
Reach minimum between Joints 1 and 5	460 mm	
Reach minimum between Joints 2 and 5	150 mm	
Reach between Joints 3 and 5	160 mm	
Maximum speed at load center of gravity	225 mm/sec	
Repeatability at constant temperature	±0.02 mm	

Table IV. Repeatability specifics and overall characteristics for six-axis robot #3.



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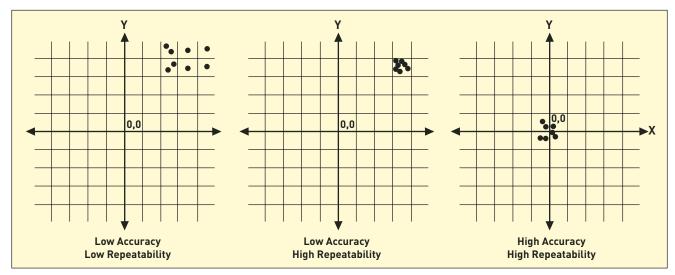


Figure 1. Two-dimensional position repeatability and accuracy of a tool tip relative to a target point (0,0).

defined, also called zeroing or mastering. Assuming good mechanical integrity and correctly defined link lengths and angular differences, 95% of a robot's volumetric positioning error can be eliminated.

To obtain the best model, each robot must undergo an elaborate procedure of commanding the arm to move through many poses, collecting measurement data, parameter fitting, and model correction. The care taken by a robot supplier in obtaining these is what sets one robot apart from another. Some robot suppliers spend little or no time obtaining these data. Rather, they have one set of parameters for all arms of a particular model. Some suppliers also assume that fixed perpendicular joints are perfectly orthogonal when that is not always the case. A robot company's design and testing philosophies dictate the integrity of the product. The details are in how a robot is manufactured, mastered, and verified.

## **Understanding Performance**

It is important to note that a robot may not perform to its specified metrics because of the way the robot is implemented. Specific to the robotics automation requirements for an OEM's application, the following aspects must be considered:

- Tool or no-tool offset and the length of the offset from the theta axis.
- Performance at a specific location in a work cell or overall work cell.

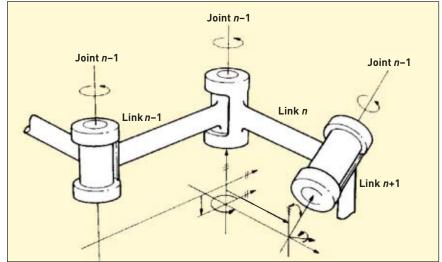


Figure 2. Relationships of serially linked axes. Mathematical relationships relate frame (n+1) to previous frame (n).

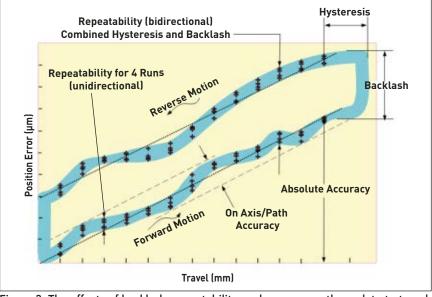


Figure 3. The effects of backlash, repeatability, and accuracy as they relate to travel.

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Figure 4. A Doppler laser functions as an easily aligned interferometer. The retroreflector is attached directly to the robot flange. Pictured is a Doppler laser kit (left) and an output graph with data obtained using high-speed acquisition mode.

- Performance in different poses.
- Payload, loaded, or unloaded (dynamic or gravity-induced change).
- Cantilever of the arm at the working positions.
- Duty cycle and ambient temperature fluctuations.

Axis gear trains are fundamental to robot motion. By far, gear-train backlash is the greatest impediment to the realization of presumed specification performance. It can be a result of insufficient axial preloads or poor meshing between drive-train components. Backlash, although always present, is almost impossible to quantify because of its dynamic characteristics. Figure 3 presents the effects of backlash, accuracy, and repeatability as they relate to travel.

In many applications, a robot's end tool is jogged to a work location using a teach pendant. By pressing a button, the location is stored, or taught, using recorded positions of each of the servo motors that make up the arm. In simple applications, work is performed by moving the robot through a series of

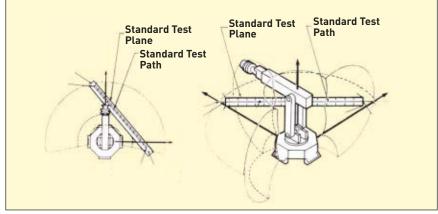


Figure 5. Isometric and plane views of the location of the standard test plane within a typical robot envelope.

taught locations while actuating some type of end-effector device. These types of applications rely solely on repeatability because the robot always approaches a location from the same direction. Because repeatability is unidirectional, and backlash is always present, it is possible that the point the robot was taught is not the point to which it will actually move. Even if the user is are aware of the presence of

backlash, it is still difficult to teach a point while approaching in a specific direction.

Robotics companies often focus on repeatability and underrate a robot's need for other performance attributes. This is far from practical. Even for the simplest application, multidirectional position repeatability—a characteristic that factors into backlash—would be a more trustworthy characteristic

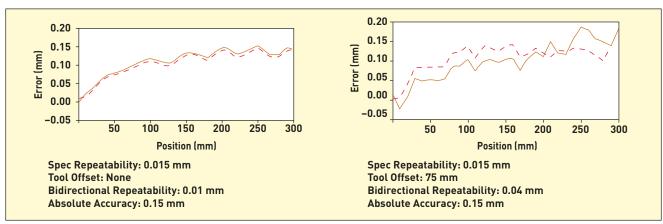


Figure 6. A comparison of a SCARA robot with and without a tool offset.

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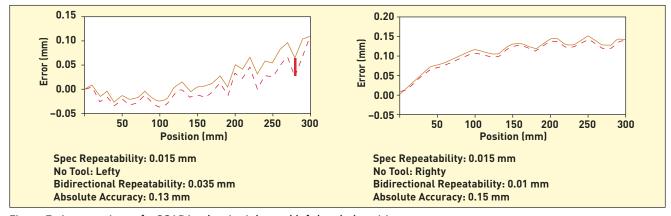


Figure 7. A comparison of a SCARA robot in right- and left-handed positions.

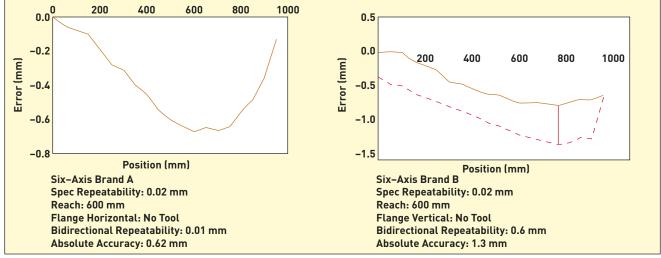


Figure 8. A comparison of the same six-axis robot in Figure 10, along the same path, in flange horizontal and flange vertical poses. Note the rapid change in accuracy (0.3 mm/100 mm) in the latter part of the first graph.

to specify. Precision is one of the pillars of robot performance, and presumably robot manufacturers want to present the best data.

A robot is a mechanically intense system—not a trusted precision device. It is important for medical OEMs to realize that an improperly integrated robot can have serious limitations, so each application must be critically assessed. Multidirectional repeatability and accuracy are the performance characteristics that are most often overlooked. As a rule of thumb, these characteristics are most important when

- It is critical to precisely teach and move to a point.
- A robot approaches a location from more than one direction.
- Its final location is altered based on an offset.
- Its final location is related to the real-world coordinate space (i.e.,

computer-aided design data for a precisely dimensioned product).

Consider the following applications:

- A move offset is calculated based on feedback from a vision system or a proximity or laser sensor.
- The robot's tool coordinate system is related to real-world space applications, such as gauging and measuring; path following, such as in dispensing; or off-line programming.
- Vision guidance, including conveyor tracking.
- Deburring, welding, and brazing.
- A multistation work cell where the robot approaches from different directions.
- Robot-to-robot work sharing.
- Replacement of a failed robot with minimal effect on location and path integrity.

These applications represent a significant portion of the duties performed by robots for medical device OEMs, and they all rely on either multidirectional repeatability or accuracy. Again, these characteristics are not included in the specifications presented by most robotics suppliers; therefore, an arm's performance in a these common applications is anything but certain.

## **Performance Realities: Test Data**

Based on industry standards for performance testing of robots, testing procedures have been developed that more closely relate robot characteristics to the types of applications previously outlined. Testing has been conducted on many robots from different suppliers using a Doppler laser (see Figure 4). A Doppler laser obtains line-of-sight position data. Under controlled environmental conditions, measurement accuracy can be greater than 100



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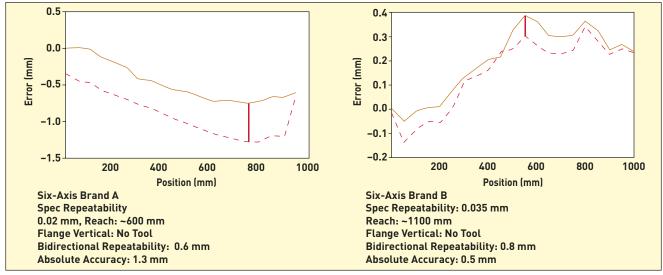


Figure 9. A comparison of two different six-axis robots along a similar path in flange vertical.

nm. The laser offers some unique features, including acquisition and plotting of position data at kilohertz frequencies.

Specialized test criteria were developed based on the ANSI standard, common medical device manufacturing requirements, and the single-line nature of the Doppler laser. The characteristics tested for include the following:

- Bidirectional repeatability.
- Absolute accuracy.
- Accuracy and repeatability differences in different poses, with different payloads (half and full), with and without a 75-mm offset tool attached, and cold and warm.

- Minimum achievable theta increment.
- Settling time moving short distances with position stabilizing to an arm's specified repeatability.
- Point-to-point cycle times.

The standard test line is within the standard plane defined by ANSI/RIA R15.05. The line reaches to the extent of the robot's reach and is set at a 45° angle to the world coordinate system (see Figure 5). The laser retroreflector is attached and offset 75 mm from the flange's center. A tool transformation is applied, and the robot traverses the path point to point while going through extreme pose differences.

SCARA robots are tested in rightand left-handed configurations to the left and right of the Y-axis. Six-axis robots are tested in a similar area, but the pose differences are flange horizontal and flange vertical in an upper configuration. All robots are tested on the same sand-filled, cast-iron base in the same environment.

Five sets of actual test data are presented (see Figures 6–10). These comparisons highlight unexpected specification performance differences that any OEM integrating or specifying a robot should be aware of.

Figure 6 presents a SCARA arm with and without a 75-mm tool offset. When a tool offset is applied to a robot about the Z-axis (theta), the minor axes move through a greater range of motion than without an offset. Because of the offset, a small angular error quickly develops into significant X-Y errors at the tool. The amount of backlash and stiction in the drive train between an axis output and its encoder dictates the minimum move increment and the inertia that the robot can reliably position. When using a tool offset, an important property is the minimum repeatable bidirectional move achievable on each minor axis (in this case, theta).

Data from a SCARA arm in rightand left-handed configurations are presented in Figure 7, which reveals some indications of kinematic integrity. A simple test is to teach a point and move to that point in different arm configurations. Measurable differences in position in different poses reveal potential

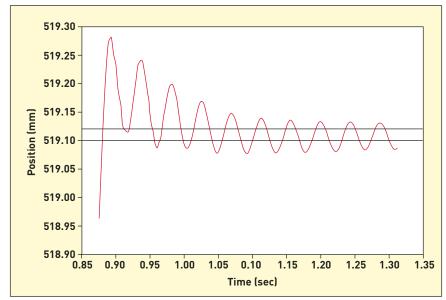


Figure 10. Within the time duration shown, this SCARA robot never settles to its inposition tolerance. The repeatability specification for this arm is 0.02 mm.

kinematic problems. Often large differences can be improved by rezeroing the robot.

Figure 8 shows results from a sixaxis arm in flange horizontal and flange vertical pose configurations. A six-axis robot is typically used to make moves that require the flange to be in any orientation except horizontal. With a turn of the wrist, this robot's characteristics change drastically. The vertical graph clearly shows the significance of backlash. With a requirement of multidirectional repeatability, the flange vertical bidirectional repeatability numbers for this robot would raise questions about its usefulness in any application. They also emphasize the need for proper robot selection.

Two different six-axis arms in a flange vertical pose configuration are shown in Figure 9. Brand B robot has better performance characteristics even though its reach is almost twice that of Brand A.

Note the erratic nature of some of the point curves in these figures. Be cognizant of approach directionality and how quickly the slopes or the direction of the slopes can change. Imagine how subtle implementation changes like reteaching a point or even executing a speed change can affect precision. Using a robot in critical medical device applications without considering these idiosyncrasies could be disastrous.

In-position settling time is critical in applications that need fast, precise placement. The settling time for a SCARA robot is presented in Figure 10. However, some arms just do not settle well. After 350 ms, this robot has not settled to its specified repeatability. In fact, this arm took almost 2 seconds to do so. Remember, the specification mentions repeatability, but it does not mention how long after the completion of the move it takes to settle to a final location. The settling-time data presented here are atypical, but again emphasize the importance of robot selection.

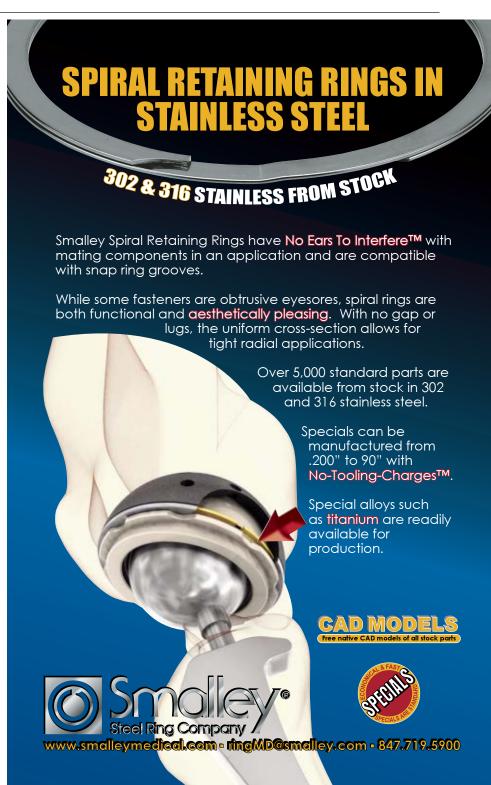
Many techniques can be used to circumvent known performance deficiencies. For instance, an assembly method that relies on unidirectional repeatability rather than multidirectional repeatability or accuracy may be feasible. Techniques that can rely solely on

resolution rather than repeatability are another possibility. To avoid costly reengineering, these techniques should be considered during initial design. Integration experience and innovation are vital to realizing if these methods are suitable for an OEM's application.

### Conclusion

The realities of robot performance are largely untold. Published specifi-

cations often fail to provide the level of information needed for an OEM to make an appropriate robot selection. Depending on the criticality of the application, independent testing is sometimes necessary. Robot performance cannot be assumed. To properly integrate and maintain a robot in a medical device application, performance metrics and how they relate to the job at hand must be well understood.



## **Fischer Connectors Inc.**



### L.U.C. Connector

Exclusively offered by Fischer Connectors, the Limited Use Connector (L.U.C.) system is designed and manufactured to take advantage of high volume savings while still allowing features such as ease of assembly, high performance standard contacts, robust shell, aesthetic design, custom circuitry, and mating with standard pin configurations in high cycle receptacles. The plastic interface can be over-molded, secured directly into a device, or become part of a snap-together back shell. The connector is designed for limited use or disposable applications such as catheters and surgical hand tools.



To avoid the risk of cross-contamination and to protect the health and lives of patients and healthcare workers, the medical industry is having more to use disposable materials. With its new Fischer L.U.C.TM (Limited Use Connector). Fischer Connectors introduces a solution that truly contributes to the competitive pricing and performance necessary for disposable medical devices. Directly mounted into a disposable handpiece, overmolded or mounted to a disposable cable, the new Fischer L.U.C.<sup>TM</sup> offers multiple configurations and optimally suits a wide array

of applications, from catheters to surgical hand tools and more. Cost-savings can easily be achieved with this new product. Mateable with all high performance Fischer panel and cable receptacles, the new Fischer disposable plug allows permanent equipment to keep working with high cycle lifetime receptacles (more than 5,000 mating cycles). Accepting a maximum cable diameter of 8.7mm, the new Fischer L.U.C.<sup>TM</sup> is available from 2 to 19 pins with solder or crimp contacts. Parts are capable of withstanding EtO and gamma sterilization processes, and conforming to the requirements of the UL/IEC 60601 directives.

1735 Founders Parkway Alpharetta, GA 30004 Contact: Richard Bickford Toll Free: 800.551.0121 Tel: 678.393.5435 Fax: 678.393.5401

Email: mail@fischerconnectors.com Web: www.fischerconnectors.com

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## Resource Planning Center

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## **Featured Products**

## **CNC Machining Center**

Designed for ¼-in. and smaller tooling, a computer numerical control (CNC) unit can machine small medical parts. The excelsiorLite comes standard with a 1.2-kW, 30,000-rpm spindle, a 20 × 20-in. machining area, and a

five-tool automatic tool changer. Other features include Windows-based 3-D control software, a keyboard and controller, Ethernet, USB ports, and remote monitoring capabilities. The unit can machine nonferrous metals such as aluminum, copper, and brass. The machining table and full enclosure



have a solid steel base, and a handheld device controls x, y, and z agility. The unit's precision ball screw provides accuracy, and its drives are covered and protected from chips and debris. Options include a pneumatic clamping system and a vacuum table that holds flat parts. The optional lightweight Quick-Pallets use a beveled boss-in-cavity system to register parts in x, y, and z for repeatability on jobs with frequent changeover. **Datron Dynamics Inc.**, Milford, NH, 888/262-2833.

www.datrondynamics.com

## Processor Board

Designed for bandwidth-intensive applications, a processor board and duo processor can be used for image

processing in medical systems. The CP6012 CompactPCI board is available with the Intel Core 2 Duo processor. The board comes with a 2.16 GHz T7400 or a low-voltage 1.5 GHz L7400 processor. High-performance re-



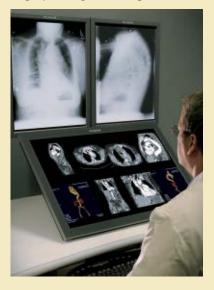
quirements are handled with a 4-Gb Ethernet interface connected via PCI Express. Customized expansions can be made on an XMC or a PMC slot for mezzanine cards. The central processing unit board is available with Linux, Windows XP, XP-embedded, or Windows Server. Configurations in the system and peripheral slots allow for integration among scalable multicentral processing unit systems. Kontron America, Poway, CA, 888/294-4558.

www.kontron.com

## Planar Systems Partners with Medical Display Companies

Planar Systems Inc. (Beaverton, OR) has partnered with NVIDIA Corp. (Santa Clara, CA), a manufacturer of programmable graphics processing technologies. Planar will bundle NVIDIA's Quadro professional graphics product with its Dome diagnostic and clinical medical displays. The Dome displays offer open architecture support, multimodality study viewing, and multiple-head configuration support. NVIDIA's Quadro technology is used for 3-D rendering. Planar also formed an agreement with Matrox Graphics (Dorval, QC, Canada) to enhance its Dome EX line of diagnostic displays. The improvement will increase grayscale resolution and provide 10-bit image data capability to healthcare manufacturers. The partnership continues

Planar's strategy to expand into specialty display markets by giving medical imaging companies more display configuration options.



## Intertek Acquires ASTA BEAB Certification Services

Intertek (London), a testing, inspection, and certification company, has acquired ASTA BEAB Certification Services (Guildford, Surrey, UK). The deal gives manufacturers based in the UK, North America, and the Asia Pacific region direct access to a wider range of certification via a single contact at Intertek. The acquisition allows Intertek to expand its electromagnetic compatibility and RoHS testing, management systems certification, and inspection services network. Intertek will also expand its services for manufacturers. The company's commercial and electrical division provides a variety of testing and certification services for the medical device industry.

## PhotoMachining Expands Facility

PhotoMachining Inc. (Pelham, NH) has added 4000 sq ft to its manufacturing plant to improve its services. The manufacturer of custom ultraviolet (UV) laser micromachining tools increased its facility to 11,000 sq ft to keep up with the demand for its UV

laser systems. A 300-sq-ft showroom was also added to display products such as refurbished systems and optics assemblies. The company's products include online workstations, roll-to-roll feeders, and machine vision and robotics. PhotoMachining's services range from R&D to high-volume production, which is conducted in a Class 10,000 facility. The company's laser drilling process can be used on catheters and angioplasty devices to enable balloon inflation or drug delivery.

## Winchester Electronics Acquires Two Electronics Companies

Winchester Electronics Corp. (Wallingford, CT) has acquired the assets of Advanced Interconnect Inc. (Franklin, MA) and Kings Electronics Company, Inc. (Rock Hill, SC). Winchester president and CEO Michael Driscoll hopes that the deal will propel the company's annual sales beyond \$100 million. The acquisitions are intended to help Winchester move into new markets and expand its technological capabilities. Advanced Interconnect manufactures fiber-optic and copper-based in-

terconnect products, including modules for OEMs in the medical electronics market. Kings Electronics produces radio-frequency connectors. Winchester Electronics has manufacturing facilities in Connecticut, Mexico, China, and Malaysia.

## Israeli Clinical Research Center Supports Studies

Hadasit (Jerusalem) has opened the Hadassah Clinical Research Center to provide the services and facilities needed for preclinical through Phase IV medical device studies. Hadasit, a subsidiary of Hadassah Medical Organization, promotes and commercializes medical products. The full-service GMP facility accommodates the protocol requests of any Phase I or Phase II study. The team at the center can also draft GMP protocols for a requesting study sponsor and train personnel to participate in the lab process.

## **3PD Buys Affinity Logistics**

Delivery company 3PD (Atlanta) has acquired Affinity Logistics Corp. (Marietta, GA). The acquisition is part of the company's plan to become a well-rounded delivery company specializing in last-mile transportation of products such as medical devices. The deal increases 3PD's projected annual revenues by nearly 50%, from \$200 million to almost \$300 million. The acquisition also increases the company's transportation capabilities to 1500 drivers and 1350 trucks nationwide.

## Lambda Research and Linos Photonics Form European Agreement

Lambda Research Corp. (Littleton, MA) has launched a partnership with Linos Photonics Inc. to distribute its optical design software in Europe and Israel. Linos, headquartered in Göttingen, Germany, will distribute TracePro software through its operations in Göttingen as well as in Milton Keynes, UK, and Champagne au Mont d'O, France. TracePro is a software tool that models and analyzes the propagation of light in imaging and endoscopy applications. Linos manufactures and dis-

tributes optical products. The company has three manufacturing facilities in Germany. It has wholly owned sales subsidiaries in the United States, France, and the UK.

## Ethox Provides Support for Monitoring System

Scivanta Medical Corp. (Spring Lake, NJ) and Ethox International Inc. (Buffalo, NY) are joining forces in the development of a catheter component for a cardiac monitoring system. Scivanta has selected Ethox to provide engineering and development support for the catheter component in exchange for the rights to manufacture the component upon regulatory approval and commercialization of the system. A technology incentive program will help provide the funding for the Hickey cardiac monitoring system. Applied Sciences Group Inc. (Buffalo, NY) has been selected to provide software engineering services for the system.

## Automation and Tooling Alliance Formed

The Automation & Tooling Alliance of North America LLC (ATANA) has been formed to provide medical manufacturers with engineering and design services. The group, composed of 12 companies, offers services including computer-aided design, reverse engineering, general machining, and molding. ATANA also provides long- and short-run machining for prototypes.



Tools include taper drills and reamers, centerless grinder work rest blades, solid carbide step drills, and workholding fixtures for product assembly. Services such as pressure testing, milling and drilling, and welding are

available. The alliance offers general machining capabilities including computer numerical control milling, turning, and grinding.

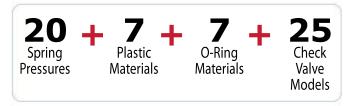
## Cambridge Consultants Expands Stateside

Cambridge Consultants (Cambridge, UK), has relocated its CEO to the company's expanded U.S. headquarters. Previously located in Boston, the office has been moved to Cambridge, MA, to allow for the addition of more U.S. staff. CEO Brian Moon's presence will help accelerate the expansion of the group's U.S. product development practices in medical devices and associated technologies. Nearly half of the company's revenue comes from U.S. firms. It will also help further the company's role as an incubator of intellectual property for spin-off and funding opportunities. Four of the company's UK-based spin-off companies have a combined market value of more than \$3 billion. ■

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## PRODUCTS SERVICES

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## **Shaft Collars**

Plastic shaft collars serve as a drill stop in cranial access kits and as stops, spacers, and locators in motion control applications. The standard line of collars is machined from Delrin and nylon. The collars are available in one- and two-piece styles and are equipped with stainless-steel fasteners. The collars come in standard sizes from ¼- to 3-in. ID and can be custom supplied in sizes up to 14-in. ID. Custom features include square, hex, and threaded bores. Materials such as PTFE can be provided to match customer design requirements. Stafford Manufacturing Corp., North Reading, MA, 800/695-5551.

www.staffordmfg.com

## **Electroluminescent Display**

A multicolor thin-film electroluminescent display can highlight important information in extreme medical conditions. Available in a space-efficient mechanical package, the EL320.240 FA3 consists of a solid-state glass panel, an electronic control circuit, and an integrated power supply. The display unit can withstand temperatures from –50° to 85°C and high levels of vibration and shock. Features include a wide viewing angle of more than 160° and an active matrix interface that is compatible with liquid-crystal displays. Planar Systems Inc., Beaverton, OR, 866/475-2627.

www.planarembedded.com





## Cable Assemblies

Circular cable assemblies are designed to meet mechanical specifications of traditional interchassis connections. The 1-by-3 Circular MT connector and adapter are housed in metal and have a stainless-steel push-twist locking ring. Intended to fit round, multifiber jackets, the connectors use 36–72 loose fibers in a single, round, and ruggedized cable that provides 360° rotation. Features include cable management clips, shutters, removal tabs, and cleaning tools. **Molex Inc.**, Lisle, IL, 800/786-6539.

www.molex.com





#### **Multipin Connector**

A multipin connector can be used in the injection molding of medical components. The connectors on the mold side are assembled by the user and interfaced with the electronics by four- or eight-channel cables. The sensors save sensitivities, allowing up to 128 analog signals to be acquired and processed for control purposes and process monitoring. For the exchange of mold inserts, the connectors for cavity pressure and temperature in the mold can be interfaced with the disconnects. The data acquisition unit can also be operated with single measuring channels. Priamus System Technologies LLC, Brunswick, OH, 877/774-2687.

www.priamus.com



#### **Laser Calibration System**

Nanometer-level motion analysis of calibration, error-mapping, and compensation for radiosurgery tools can be achieved with a laser calibration system. The XL-80 coordinates measuring machines, lithography equipment, advanced machine tools, robots, and assembly systems. The unit has a linear measurement speed of 4 m/sec with a resolution of 1 nm. Its system accuracy of ±0.5 ppm is maintained over an operating temperature range of 0° to 40°C. The XC-80 Intelligent Sensor system maintains accuracy against variations in temperature, pressure, and humidity by updating the environment factor every seven seconds via a USB link. The reduced dimensions of the laser head and stage enable mounting on a magnetic base. The unit can also be placed directly on a table for coordinate-measuring machine calibration. Renishaw Inc., Hoffman Estates, IL, 847/286-9953.

www.renishaw.com



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## Surface Modification System

An electron-beam (E-beam) process modifies surface characteristics of any metal with exact tolerances and repeatability. Surfi-Sculpt has a range of medical applications, from growth-fostering texture on implant surfaces to microscopic patterns on tool grips. On ferrous and nonferrous metal, the technology creates precise, detailed protrusions and intrusions that can be built and fashioned as separate operations to allow for a range of textures,



shapes, and patterns. The company also offers laser and E-beam fusing, laser

cutting and drilling, and abrasive waterjet cutting. **EBTEC Corp.**, Agawam, MA, 413/786-0393.

www.ebteccorp.com/innerspace

#### **Microcontrollers**

An 8-bit microcontroller family can be used in voice-activated medical applications as well as in advanced



wheelchairs. The PIC18F87J50 line of controllers features an integrated USB 2.0 transceiver that operates at 12 Mbyte/sec. The microcontrollers offer nanowatt technology for low power consumption in sleep mode, up

to 65 input-outputs, and 4 Kbyte of random-access memory. The line also has up to 128 Kbyte of flash program memory, which can be updated in circuit, and a rich peripheral set, including a 12-channel, 10-bit analog-to-digital convertor and a parallel master port for connection to external memory and displays. Stand-alone USB operation eliminates the need for a separate USB interface. Microchip Technology Inc., Chandler, AZ, 480/792-7200.

www.microchip.com

#### **Compact Backplanes**

Backplanes are available for medical electronics applications such as diagnostic imaging, radiation therapy, in vitro diagnostics, and robotic surgery. CompactPCI systems are available in a variety of sizes, ranging from 1-U, 2-slot 64-bit systems to 7-U, 8-slot 64-bit systems. The systems have vertical and horizontal board mounting options and a range of cooling and



#### **Precision Medical Extrusions** Single Lumen All Thermoplastic materials. Multi-Lumen incl. PVC, LDPE, MDPE, HDPE, Profiles Polypropylene, Urethane, Bump Tubing Nylon, Pebax, ABS, Hytrel, Custom Santoprene, Polycarbonate, Kraton, PET, PES, PVDF, FEP Compounds Process Capabilities include extrusion coatings, balloon and shrink tubings, vacuum sizing. Prototype or production quantities. Phone or FAX your requirements for immediate quotation to: Medical Extrusion Technologies, Inc. Website: www.MedicalExtrusion.com 26608 Pierce Circle Murrieta, CA 92562 Email: MET@MedicalExtrusion.com 800-618-4346 • 951-698-4346 • Fax 951-698-4347

power options. The backplanes come in 3-U and 6-U heights in 32- and 64-bit versions with 1–16 slots. PXI backplanes and bridges provide high-frequency-noise suppression and a high mean time between failure via ceramic capacitors. Custom-designed backplanes are also available. Pentair Electronic Packaging, Golden Valley, MN, 763/545-1730.

www.schroff.us

#### Structural Adhesives

A company offers a guide detailing its structural adhesives for medical devices. Featured products include Bondmaster tube set-bonding adhesives,



which offer accelerated cure times, reduced stress cracking, and the ability to bond dissimilar materials. Also available are components-bonding adhesives that resist harsh environmental conditions, can be applied rapidly, and provide good bond quality. The guide includes reference charts with specifications and application examples of almost a dozen medical ultraviolet and medical epoxy adhesives. National Adhesives, Bridgewater, NI, 800/797-4992.

www.bondmaster.com

## Medical Diagnostic Sensor Inks

Two silver chloride inks are available for medical diagnostic sensor applications. The conductive inks are designed for use on defibrillator pads as well as disposable electroencephalograph and electrocardiogram sensors. The crease-resistant AGCL-510 and AGCL-675C inks adhere to polyester, polyimide, polycarbonate, vinyl, urethane, and other plastic substrates. AGCL-675C is designed to optimize the electrode surface contact area by providing a rough, textured surface after drying. The inks can be custom blended, such as adjusting the propor-

tion of chloride to silver, to meet specific resistance values and electrical conductivity requirements. Conductive Compounds Inc., Londonderry, NH, 603/437-6221.

www.conductivecompounds.com

#### **Coating Services**

Medical device manufacturers can use coating services to enhance product performance. A company's services include hard, low-temperature coatings to provide increased wear life. The coatings can help customers solve problems such as wear and galling, where similar materials begin to bond with each other instead of smoothly riding back and forth. Armoloy of Connecticut Inc., Bristol, CT, 860/583-7088.

www.armoloyct.com

#### **Power Film Resistors**

An expanded series of power film resistors are suitable for medical power supplies and equipment. The MP series has wattage ratings from 10 to 145 W in various through-hole and surfacemount styles to 1% and 50 ppm. The precision TO126 and TO220 resistors have tolerances as tight as 0.025% and tight 2-ppm temperature coefficients. RCD Components Inc., Manchester, NH, 603/669-0054.

www.rcdcomponents.com

## Miniature Push-Button Switches

Miniature push-button switches have a zinc alloy and velour chrome-plated exterior with a vandal-resistant interior housing. The Series 57M has a housing diameter of 0.73 in. and comes in either a center spot light-emitting



diode or nonlit configuration. The switches are available with printed circuit or solder terminals. They mount into panel thicknesses from 1.5 to 3 mm. Operating temperatures range from -40° to 185°F. Mechanical life of

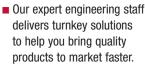
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www.itwswitches.com

#### **Evaluation Kits**

Two evaluation kits are designed for a class of integrated communication microcontrollers used in medical instrumentation. The Stellaris kits include ARM RealView Microcontroller Development Kit software. The EKK-LM3S6965 kit features fully integrated 10/100 Ethernet capability, and the EKK-LM3S2965 has an integrated controller area network (CAN) with a separate Stellaris LM3S2110-based CAN device node board. Both evaluation kits have standard ARM 20-pin ITAG debug connectors with input and output modes and a peripheral driver library. Other features include user light-emitting diodes, navigation switches, select push buttons, power and debug USB cables, and a compact disc with datasheets, schematics, application notes, and programming examples. Luminary Micro Inc., Austin, TX, 512/279-8800.

www.luminarymicro.com

## Precision Orifices and Filters

A company offers precise orifice and filter inserts in a variety of sizes and fittings. These inserts can be used for micrometering of small amounts of oxygen and other medical gases in valves, regulators, and ventilators. They can also function as dispense tips



for various medical fluids. Sizes range from 0.0004 to 0.081 in. in more than 150 distinct sizes. Flow rates start at less than 1 sccm. These precise orifices are nonoxidizing, chemically inert, and have high wear resistance. The prod-

ucts are manufactured using laser drilling and wire lapping methods. Bird Precision, Waltham, MA, 800/454-7369.

www.birdprecision.com

#### **Protected Contact System**

An IP67-protected contact system increases the safety and performance of switches in critical medical applications. The MSM contact system is protected by a seal that is integrated into the mechanical push-button and a seal



ring secured to the housing. The switch has an electrical rating of 6 A and 250 V ac. Alternative electrical ratings and additional types are also available. Mounting diameters for the series of 1.7-mm switches are 16, 19, 22, and 30 mm. Point and ring-illuminated versions can be used for applications in which optical-status indications are needed, such as in dark conditions. Schurter Inc., Santa Rosa, CA, 707/636-3000.

www.schurter.com

#### Single-Board Computer

A single-board computer provides smooth migration for medical applications without the extensive hardware and software redesigns associated with moving legacy peripherals to newer buses. Measuring 115 × 165 mm, the ReadyBoard 620 combines the 500-MHz Geode LX 800 processor with 128-Kb level 2 cache. It also has a set of onboard legacy input-outputs, including two ports with RS-485 support, a parallel and floppy port, integrated graphics, 10/100 Ethernet ports using an Intel 82551 controller, and



USB 2.0 ports. Most of the ports use standard PC-style connectors to minimize cabling. Bus expansion is available using the standard stacking PC/104 Plus interface. Ampro Computers Inc., San Jose, CA, 408/360-0200.

www.ampro.com

#### **Testing System**

A company's testing system is used to measure and record radial stiffness and hoop strength of interventional medical devices such as balloon expandable stents, embolic filters, and collagen plugs. The 5544/RX system comes



with a Bluehill software package that minimizes the amount of verification and validation work that a manufacturer must perform on testing systems. The system's low-force capability is compatible with a variety of stent sizes and configurations. It can also be used for standard tensile and compression testing for catheter tubing, nitinol, and surgical devices and materials. Instron, Norwood, MA, 800/564-8378.

www.instron.com

## **Watson-Marlow Bredel Inc.**

Watson-Marlow Bredel, the leading manufacturer of peristaltic pumps, is proud to offer its 313D medical grade peristaltic pumps for, irrigation, cooling or waste removal applications in the medical device industry.

The 313D pump is ideal for medical applications with flow rates from 0.25 to 3000 ml/min. All fluid being pumped is completely contained within the tubing, so cleaning the pump is as simple as replacing a tube. With a pumphead that opens wide and then clamps and stretches the tube as it closes, the tube is in the position to deliver optimum pumping performance every time. The process is intuitive and fool-proof, and there are no extensive tools, adjustments, or training required.



The 313D's design and styling is cutting edge, and the pump can be ordered in custom colors to match any OEM's equipment. Typical options for the pump include an open indicator switch, fixed or variable tube clamps, and private labeling. These sanitary pumps have no valves or seals, can run dry without damage, and pump against an 860 mmHg vacuum. The 313D can be purchased as a pumphead only, or with gear motor drives that are available in AC, DC, Stepper Motors, and Brushless DC configurations.

The 313D can be customized to work with any pump grade tubing. Watson-Marlow manufactures tubing in two USP Class VI materials: PumpSil®? pump grade platinum

cured silicone, or long-life Bioprene®?TPE Tubing. These tube materials are available in twelve standard sizes to match any flow range, pressure or suction requirements. Watson-Marlow is an ISO 9001: 2001 Design for Six Sigma company with over 50 years experience providing quality products to OEM customers. Our state-of-the-art manufacturing systems and design practices ensure the best quality at the best price. Our experienced team will provide on-time delivery and product support. For more information, please visit www.watson-marlow.com.

OEM Division Watson-Marlow Bredel Pumps support@wmbpumps.com 978-658-6168



#### Solenoid Valves

A line of solenoid valves with tab coils can be used in dental applications as well as medical instrument sterilization equipment. The 204 and 304 series, two-way and three-way valves respectively, are available in normally



open or closed configurations. Maximum flow rates are delivered through orifice sizes that range from ½2 to ½2 in. The valve line is manufactured with ½-in. port size national pipe thread connections. The RoHS-compliant series has also been UL-evaluated for elevated temperatures. Parker Hannifin Corp., New Britain, CT, 860/827-2300.

www.parker.com/fcd

#### Peristaltic Pump

A matchbox-sized peristaltic pump is designed for automated medical applications. Smaller than syringe pumps, the 400 F/A pumps eliminate the need



for valves, provide continuous flow capability, and have tight dimensional tolerances. The self-priming pumps have repeatability of 99.5%. They can accommodate flow rates from 0.1 µl to 350 gal/min and withstand pressure up to 232 psi. The pumps are also reversible for back-flushing lines. They can run dry indefinitely without damage and provide up to a 30-ft suction lift. Watson-Marlow Bredel Inc., Wilmington, MA, 800/282-8823.

www.wmbpumps.com

#### **Industrial Dispenser**

A dispensing pump is suitable for medical component assembly. The IDS2000 dispenser has a valveless ceramic piston pump that is direct-coupled to a precision stepper motor. The stepper motor and driver are



packaged in a splashproof stainlesssteel enclosure. The system dispenses quantities from  $2 \mu l$  to 7 ml and is appropriate for dispensing solvents, lubricants, cleaning agents, and adhesives. The unit comes with a quick-run module, power supply, and foot switch. Fluid Metering Inc., Syosset, NY, 800/223-3388.

www.fmipump.com

#### **Ball Valves**

Specialty ball valves are used in highpurity medical manufacturing applications. The Series 6 EM-Technik valves



are installed in wet-process applications in which aggressive gases and liquids are shut off, isolated, mixed, or distributed. The series is available in ¼- and ½-in. versions. Standard valves are made with female national pipe threads and fluorocarbon rubber Orings. The valves can be made from polypropylene, polyvinylidene fluoride, and perfluoroalkoxy in a variety of types, from a two-way to a five-way ball valve. The valves are available with electric or pneumatic actuation. Asahi America Inc., Malden, MA, 800/343-3618.

www.asahi-america.com

#### **Cartridge Valve**

A cartridge valve can be used to dispense materials used in manufacturing medical devices. The CV629 is a lightweight valve for high-cycle applications of silicones, lubricants, and some adhesives, which would be applied either as a liquid gasket or unit



shot for parts assembly. The valve can also be integrated into an automated system where the quick-change, one-piece cartridge seal ensures minimal maintenance and reduced downtime. The strike is adjustable and the valve is recommended for microshots or fine beads. Maximum fluid pressure is 300 psi. I&J Fisnar Inc., Fair Lawn, NJ, 201/796-1477.

www.ijfisnar.com

## Sekisui Voltek, LLC

Sekisui Voltek, LLC, a part of the worldwide network of Sekisui companies, is a global leader in the development and production of crosslinked, closed-cell polyolefin foams. For over 35 years, Sekisui Voltek's innovative foam solutions have been used for a wide variety of applications within the transportation, tape and healthcare, building and construction, sports and leisure, and general industrial markets.

The company has three primary foam processes; Volara® - irradiation crosslinked polyolefin foam in roll, and laminated sheet form, Volextra® - an extrusion coated Volara® composite and Minicel® - a chemically crosslinked foam in bun form. Within each process modification of



elements such as resin selection, additives, foaming technologies, cross-linking parameters, density and thickness, performance parameters that customers need are achieved.

Sekisui Voltek's foams provide low-cost, lightweight. high-performance material options to a wide variety of markets. Their high strength-to-weight ratio, pleasing aesthetics, texture, performance capabilities, and other properties offer significant advantages over traditional materials such as fabric, rubber foam, solid plastics, paper, and leather.

Sekisui Voltek does whatever it takes to help customers solve their challenge — they'll even create a new product designed specifically for them. Application engineers can determine if the best solution is one of the existing product grades, or if the unique demands of the application call for development of a new grade. With the help of Authorized Fabricating Distributors, Sekisui Voltek can also utilize other related technologies, like press molding, vacuum forming, waterjet profile cutting, die cutting or lamination of cross-linked, closed-cell foams to a variety of other substrates.

The company has manufacturing facilities in Massachusetts and Michigan, and sales offices located throughout the United States. For more information about Sekisui Voltek, contact the company at 100 Shepard Street, Lawrence, MA 01843. Phone: (978) 685-2557. Fax: (978) 685-9861. Or visit their website at http://www.SekisuiVoltek.com.

#### **SEKISUI VOLTEK, LLC**

100 Shepard Street, Lawrence, MA 01843 Tel: 800-225-0668 Fax: 978-685-9861 www.SekisuiVoltek.com

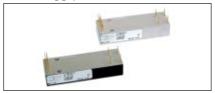






#### **Precision Filament Supplies**

Nonisolated precision filament supplies can be used with x-ray equipment. The center-tapped, low-voltage FIL-5V-3A supply is rated for 0–5 V dc at



0-3 A. In constant current mode, the current control sets output current and the voltage control sets the voltage unit. In constant voltage mode, the voltage control sets the output and the current control sets the current limit. The units have automatic crossover between modes. Between 26.4 and 21.6 V dc, output regulation is less than 0.01%. The units have a temperature coefficient of 15 ppm/°C in constant current mode. Options include wraparound shielding, an eared mounting plate, and finned heat sinks. Ultravolt Inc., Ronkonkoma, NY, 631/471-4444.

www.ultravolt.com

#### **Homopolymer Acetals**

Designed for use in medical devices and equipment, homopolymer acetals can withstand repeated autoclave cycles and can be sterilized with steam



and EtO. The materials are alloyed with elastomers and modifiers to increase impact strength and elongation. The medium-viscosity Aardalloy 3300 is a high-heat acetal that provides dimensional stability with deformation temperatures up to 315°F. The high-viscosity 3326 resin has the same high degree of chemical resistance and low fuel permeability found in unfilled acetals. It can be used in applications that require deformation temperatures up to 212°F. Both materials can be processed on conventional equipment and

can be welded, bonded, and machined. They are available in white and black. **Aardvark Polymers**, Lambertville, NJ, 617/803-8682.

www.aardvarkpolymers.com

#### **High-Pressure Transducers**

Pressure transducers are suitable for medical instruments. Measuring less than 1 in. in diameter, the Compact



3100 series has a stainless-steel construction that is resistant to corrosive media. The transducers come in pressures ranging from 100 to 30,000 psi. Output voltages are 0–5, 1–5, 0.5–4.5, 1–6, and 0–10 V dc. They are also available in 0.5–4.5 V radiometric. Pressure fittings include national pipe thread, unified national fine thread, British standard parallel thread, and metric. Setra Systems Inc., Boxborough, MA, 800/257-3872.

www.setra.com

#### **Electrical Safety Test Guide**

A guide to the IEC 62353 electricalsafety testing requirement is available. The test standard defines requirements to ensure the in-service electrical safety of electromedical equipment and systems. The booklet is designed for biomedical engineering personnel, medical equipment service engineers, and medical device manufacturers. It explains the standard requirements and



includes information on definitions, symbols, different leakage measurements, schematics, pass-fail limits, and single-fault conditions. **Rigel Medical**, Peterlee, UK, +44 191 5878744.

www.rigelmedical.com

## Switch-Mode Power Supplies

A company offers a series of highdensity ac-to-dc switch-mode power supplies. The HD160 series provides up to 160 W in a 2 × 4-in. footprint. Standard output voltage set points are 5, 12, 24, and 48 V dc. The singleoutput power supplies feature universal ac input from 85 to 264 V ac and active power factor correction. The RoHS-compliant series delivers operational efficiencies up to 90% with a power density exceeding 18 W/cu in.



The supplies provide protection against overtemperature, overcurrent, and overvoltage conditions. **Digital Power Corp.**, Fremont, CA, 866/344-7697.

www.digipwr.com

## Vacuum-Encapsulated Inverters

Vacuum-encapsulated inverters are designed for backlighting medical displays. The series of inverters provides cold cathode fluorescent lamp (CCFL) liquid-crystal displays with resistance to shock, vibration, and humidity. They operate at 80-85% efficiency and have customized magnetics that are self-shielding to minimize electromagnetic and radio-frequency interference. The E200II can power one or two CCFLs with up to 8 W of output power. Measuring  $0.42 \times 0.75 \times 2.98$ in., the SE series provides up to 5 W of output power for single CCFL backlights. The SE2 line, which has the same measurements, is for two-lamp

## **AST Products, Inc.**



AST Products, Inc. (AST), is a world leader in medical device coatings. Their proprietary water-based technology, BioLAST<sup>TM</sup>, offers the medical device industry specialty coatings that are technically superior, easy to use and environmentally friendly.

AST's comprehensive research and development capabili-

ties are the foundation of their personalized approach to coating solutions. This solid background of research expertise coupled with AST's partnership approach, allows them to create a coating specific to their clients' individual needs.

Technological advances in the design and development of medical devices have greatly improved the diagnostic and therapeutic



capabilities in medical care. However, the materials that are used can often bring undesirable complications to the body including bacterial infection, blood clots and tissue trauma. These clinical issues can be addressed using AST's flexible BioLAST<sup>TM</sup> coating technology, which can be customized to incorporate a variety of properties.



The BioLAST<sup>TM</sup> platform includes LubriLAST<sup>TM</sup>, lubricious coating; Repela-COAT<sup>TM</sup>, lubricious antimicrobial coating; Hydro-LAST<sup>TM</sup>, hydrophilic surface treatment; pHree-COAT<sup>TM</sup>, anti-encrustation

coating; HemoLAST $^{TM}$ , anti-thrombogenic coating; VascuLAST $^{TM}$ , drug eluting coating; and ParyLAST $^{TM}$ , a plas-

ma-enhanced biocompatible parylene coating that adheres better than traditional parylene. AST also offers low protein-binding coatings, and custom surface treatments.

Offering a broad range of competitively priced, organic solvent-free and water-based medical device coatings, AST serves a number of



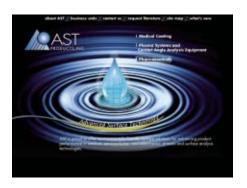
medical specialties that include cardiovascular, neurovascular, urological, diagnostic, ophthomological, and gynecological applications. Examples of medical devices that use AST's coatings include catheters, stylets, cannulas, endoscopes, stents, guidewires, guiding catheters, ophthalmic surgery devices and diagnostic devices.

The diversity of available coatings combined with AST's customized approach enables the delivery of a product that meets all coating specifications. The company's strength lies in its supe-



rior technology, product reliability and partnership skills. AST's partnership approach results in successful relationships built on dependability and experience. Contact Us:

AST Products, Inc. 9 Linnell Circle Billerica, MA 01821 Phone: 978/667-4500 Fax: 978/667-9778 Website: www.astp.com



configurations. Endicott Research Group Inc., Endicott, NY, 800/215-5866.

www.ergpower.com

## Medical Diagnostic Displays

A range of liquid-crystal displays are designed for medical diagnostic equipment. Display options include backlight inverters as well as display interface cards and adapters. Touch screens,



attachments, and controllers are also available. Displays can be manufactured with light-emitting diode backlighting and brightness enhancements. Other options include standard and custom interface cabling and a Class 1000 cleanroom. Apollo Display Technologies LLC, Ronkonkoma, NY, 631/580-4360.

www.apollodisplays.com

#### Dc-Dc Convertor

A series of convertors can be used with battery-operated medical equipment. The isolated TMR-2WI series allows a wide input range to accommodate the output voltage swing that



is common in batteries. The RoHS-compliant series consists of 14 models that have 9–36- or 18–75-V dc input ranges with single and dual outputs from 3.3 to 15 V dc. The convertors have efficiency up to 84% and operate in temperatures from 40° to 75°C at

full load. Features include remote on and off, 1000-V dc isolation, and short-circuit protection. Traco Electronic AG, Zurich, Switzerland, 866/588-1750.

www.tracopower.com

#### **Aluminum Extrusion**

A company provides extrusions for prosthetics, x-ray machines, and other medical equipment. Aluminum extrusion and sheets are available, and the company recycles the customer's excess material. The company offers special packaging and time-sensitive delivery options. O.C. Aluminum Inc., Houston, TX, 866/483-8806.

www.ocaluminuminc.com

#### Right-Angle Gear Drive

Right-angle gear drives are suitable for continuous passive motion devices used in orthopedic surgery. Weighing 3 oz, the Miniature RA gearbox uses



permanently lubricated gear drives, hardened-steel helical gears, and non-metallic bearings. The drive is rated at 1800 maximum rpm and ½ horsepower continuous duty. It features a choice of one or two input shafts as well as 1:1 or 2:1 gear ratios. Other options include right- or left-hand configuration and nylon or aluminum housing. The drives can be operated in either direction. Torque Transmission, Fairport Harbor, OH, 800/544-6642.

www.torquetrans.com

#### Fluidic Systems

A company manufactures solenoid valves as well as level, flow, and pressure sensors for medical applications. The fluidic systems can be used in dental, surgical, and medical imaging

equipment. The company can integrate multiple valve types, tube and pipe fittings, sensors, and filters into the systems. Gems Sensors & Controls, Plainville, CT, 800/378-1600.

www.gemssensors.com

#### ID and Labeling Catalog

A catalog has technical specifications for wire, harness, and label identification products as well as hardware, software, and printers. It also has details



about specialty products such as radiofrequency tags, prep-print services, and tube and pipe identification labels. Highlighted products include heat-shrink cable markers, highperformance labels, self-laminating labels, and preprinted wire and cable markers. An assortment of thermal transfer labels, dot-matrix labels, and laser labels are also in the catalog. Tyco Electronics Corp., Harrisburg, PA, 800/522-6752.

www.tycoelectronics.com

#### **Engineering Sample Kit**

An engineering sample kit features RoHS-compliant parts used for incircuit evaluation. The kit's samples



can be used on printed circuit boards (PCBs) in medical devices. More than 20 samples of test points and jumpers, fuse clips, and battery contacts are included. The multicompartment box contains standard-, low-, and ultralow-profile devices as well as surfacemount and thru-hole parts. The kit includes the TP-101 series of PCB



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#### PRODUCTS & SERVICES >>

and surface-mount technology test points, the ATP-402 test point series, the MC-10 fuse clip series, and the BC-501 battery contact series. A catalog comes with the kit. Components Corp., Denville, NJ, 866/426-6726.

www.componentscorp.com

#### **External Adapters**

A family of external adapters meets safety standards for medical applications. The Medline EXM 80 line provides up to 80 W of output power in a wall-mount configuration. The series has single outputs of 12, 15, 18, 24, or 48 V dc. Features include exchangeable ac plugs for universal use, low leakage current, and a front-edge fly-back design with low component count. Powerbox USA Inc., Broomfield, CO, 800/444-1461.

www.powerbox.info

#### **Heat Transfer Labels**

A company offers contract printing services for labels designed for the medical industry. Four-color process printing is available for Variable Data Digital Heat Transfer Labels. The company can mark catheters in a print area of 100 cm or 1000 mm in a single cycle. Labels for syringe barrels, silicone products, and other product types are available. Comdec Inc., Newburyport, MA, 800/445-9176.

www.comdecinc.com

#### **Nylon Casters**

Casters designed for medical equipment are made with glass-filled nylon



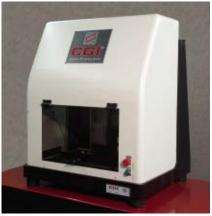
for strength and durability. The NG series wheels have sealed precision bearings with 4- and 5-in. diameters. Thread guards are fully integrated to prevent the pickup of string, sutures,

and foreign debris. Free swivel, direction lock, and total lock models are available. Performance options include Type 304 stainless-steel fitting and components, antistatic models, and Prevenz antimicrobial models. Custom colors are available. MedCaster Inc., Albion, MI, 866/462-9700.

www.medcaster.com

## Scanning Inspection System

An inspection system captures the complex internal and external geometry of small injection-molded medical



parts. The CSS 300 cross-sectional scanning inspection system is an alternative to technologies for first-article inspection, reverse engineering, failure analysis, and tooling qualification. The system combines the company's cross-sectional scanning technology with its Spec.Check inspection software. Crump Group Inc., Eden Prairie, MN, 952/937-2005.

www.cgiinspection.com

#### Single-Output Power Supply

Single-output power supplies are designed for medical applications that range from 40 to 65 W. Providing 35% more energy efficiency than conventional models, the Ault MW174 line's universal outputs range from 100 to 240 V ac. The power supplies are available in a desktop style with output voltages of 5, 9, 12, 15, 18, and 24 V. The supplies meet EMC requirements as well as those of safety agencies such as UL and IEC. SL Power Electronics Corp., Ventura, CA, 763/592-1900.

www.slpower.com

### **Tech-Etch**

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Tech-Etch has been a leader in the manufacture of engineered parts, EMI/RFI shielding products, and flexible printed circuits for the medical industry for over 40 years. Advanced production techniques enable customers to save money while meeting demanding scheduling requirements.

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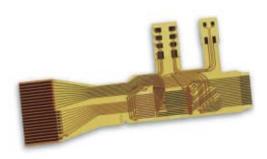


Specialty materials have characteristics attractive to the medical industry for implants, springs, cathodes, blades, and stents. Photoetching and precision forming dies offer the flexibility of manufacturing prototype quantities and large production runs without the high cost and long lead times associated with hard tools. Part thickness ranges from .0005" and up. Forming, laminating, assembly and finishing are also available.

## EMI/RFI Shielding for medical devices and electronic enclosures

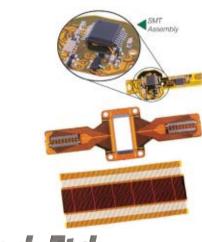
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## **Emerging Strategies in Product Development**

roduct development almost always includes some mention of technology and what can be done to harness it for a new product.

A conference session chaired by Jim Takach and Tim Durst of PRTM (Waltham, MA) at MD&M Minneapolis will focus on several technological aspects of product development and discuss how to turn these ideas into a strategy. The first topic, titled "Gaining Advantage through Technology Strategy," discusses how important it is to invest in technology, to have a structured methodology in place for nurturing technology to its full potential, and to rigorously tie certain technologies to product portfolios.

"[A company's] technology scouting should align with its objectives, but [the technology] may not necessarily be tied to a specific product line. As

technologies are screened and matured, they need to be linked to the products that they will ultimately enable," Takach says.

But it may not be easy to determine how or how much to invest, or which technology investment is right for a company.

"I am often asked how [much money] or what percentage of R&D should be invested in technology, and there is no exact answer. Ultimately a company needs to deliver innovative products—and to the extent that technology plays a role, the investment needs to be commensurate," Durst

Takach notes that companies should also have proper governance and de-

Find information on registration, travel, and exhibitors at the MD&M Minneapolis Web site:

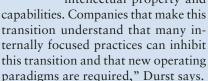
www.mdmminn.com

cision making in relation to new technologies, effective methods to assess technology readiness, and adequate structure in transferring technology to

product.



"In general, companies are starting to understand that markets are changing quickly and internal capabilities need to be complemented with external intellectual property and



Old models of innovation may have included a licensing and business development group, for example, but

R&D departments would not be tightly linked with these groups. Durst says that under new models, capabilities can be more extensive and unified.

Takach believes that in-house capabilities can be enough given the right market, competition level, and capabilities. However, companies often find partners to help them meet objectives, including:

- Reducing overall development cost and time to market.
- Providing new ideas and technologies.
- Licensing technologies, including those that no longer align with the company's strategic direction.
- Reducing risk.

What it comes down to is a company's continuous drive to be innovative and make better products. A company's own capabilities have not become inferior, Durst says, but there is an increasing emphasis on delivering innovative products to market in a shorter window than before. Such innovative products are often driven by advanced technology. "Even with good internal technology investment, any individual company would be foolish to believe it will always develop the best technology."

–Lawrence Lloyd



Takach

#### **KEY INFORMATION**

MD&M Minneapolis 2007 Conference and Exposition:

October 16-18

#### Attendee and Exhibitor Information:

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## MicroMo Electronics, Inc.

#### **Who We Are**

MicroMo Electronics, Inc., a member of The FAULHABER Group, offers the world's largest consolidated portfolio of miniature and micro drive system technologies available from one partner in the world today. MicroMo specializes in the design and manufacture of complex, high precision miniature and micro drive systems for challenging areas of application such as medical devices, handling automation, telecommunications, and precision optics. Our core competency is in providing precision miniature DC drive systems consisting of a brush, brushless, or stepper motor in combination with a gearbox, encoder, and control electronics. MicroMo application engineers are experts in motion control systems and partner with customer design engineers on mechanical and electrical design. MicroMo can manufacture complete system assemblies or subassemblies and micromechanical systems.

#### Quality

The FAULHABER brand name is known worldwide as a symbol of high quality. MicroMo is ISO9001:2000 qualified as are all of the members of the FAULHABER Group. We believe in building quality into our manufacturing and service processes.

#### **Assembly & Production**

MicroMo is capable of manufacturing products in lot sizes ranging from a single unit to multimillion units. Whether customized to our customer specifications or a standard product, all FAULHABER Group products are designed specifically for efficient, high quality production. We continually adapt and improve our produc-

tion capacities to address the growing needs of our global customers. The FAULHABER Group is a global producer with locations all over the world

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Since the invention of the self-supporting, progressive, skew-wound, ironless rotor coil in the 1940's by Dr. Fritz Faulhaber, the FAULHABER Group has innovated new products. We invented the industry's first high resolution integrated incremental encoder and the world's smallest commercially available brushless gear motor. We employ over 100 R&D engineers charged with pushing the limits of micro technology to bring greater value and new market opportunities to our customers.

of the future. We expect to continue our reputation for excellence by providing industry leading technology, application expertise, and product quality."

- Ted Severn Director of Sales and Marketing



#### Service & Support

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"MicroMo's vision is to become the best motion solution provider for miniature mechanisms in North America. We have partnered with our customers to find innovative engineering solutions to their most challenging problems. We are designing smaller, more powerful DC micromotors, gearboxes, encoders, and control electronics to drive the technologies



#### September Highlights

**September 6-7:** Calibration in the FDA-Regulated Industry, New Brunswick, NJ. Contact: Center for Professional Advancement, East Brunswick, NJ, 732/238-1600.

**September 9–12:** Optics East, Boston. Contact: The International Society for Optical Engineering, 888/504-8171.

**September 12–13:** Medical-Grade Polymers, Philadelphia. Contact: Applied Market Information Ltd., Bristol, UK, +44 117 9249442.

**September 16–21:** EOS/ESD Symposium and Tutorials, Anaheim, CA. Contact: Electrostatic Discharge Association, Rome, NY, 315/339-6937.

September 21: Understanding the Japanese Medical Device Market and Pharmaceutical Affairs Law, Philadelphia. Contact: BSI Management Systems, 800/862-4977.

September 23-26: Regulatory Affairs Professionals Society (RAPS) Annual Conference & Exhibition, Boston. Contact: RAPS, Rockville, MD, 301/770-2920.

September 24-26: Science and Risk-Based Approach to Commissioning, Qualification, and Validation, Amsterdam, The Netherlands. Contact: Center for Professional Advancement, East Brunswick, NJ, +31 20 6382806.

September 25: Understanding ISO 13485:2003, San Diego. Contact: BSI Management Systems, 800/862-4977.

**September 25–26:** Applied Regulations for Medical Device Studies, Web seminar. Contact: Clinical Device Group Inc., Chicago, 773/489-5706.

## Upcoming Trade Shows from Canon Communications

**September 19–20:** MEDTEC Ireland, Galway, Ireland, www.medtecireland.com

**September 24-27:** National Manufacturing Week, Rosemont, IL, www.manufacturingweek.com

**September 25–27:** Assembly Technology Expo, Rosemont, IL, www.atexpo.com

**September 25–27:** Quality Expo, Rosemont, IL, www.qualityexpo.com

October 16-18: Medical Design & Manufacturing Minneapolis, Minneapolis, www.mdmminn.com

**October 17–18:** MidPak, Minneapolis, www.midpakshow.com

**October 30–31:** Assembly New England, Boston, www.assemblynewengland.com

October 30-31: NEPCON, Boston, www.nepconeast.com

**October 30–31:** OEM New England, Boston, www.oemnewengland.com

#### Contact:

Canon Communications LLC, Los Angeles, 310/445-4200, www.canontradeshows.com

September 26–28: Institute of Electrical and Electronics Engineers (IEEE) International Conference on Biometrics: Theory, Applications, and Systems, Washington, DC. Contact: IEEE, Piscataway, NJ, 574/631-9978.

September 26-29: Biomedical Engineering Society (BMES) Annual Fall Meeting, Los Angeles. Contact: BMES, Landover, MD, 301/459-1999.

#### October Highlights

**October 1–3:** Medical Innovation Summit, Cleveland. Contact: CCF Innovations, 216/444-5757.

October 3: Current Issues in Medical Device & Pharmaceutical Sterilization, Iselin, NJ. Contact: STERIS Isomedix Services, Mentor, OH, 440/392-8057. October 3: Regulatory Update: Clinical Trials, Web seminar. Contact: Regulatory Affairs Professionals Society, Rockville, MD, 301/770-2920.

October 9-10: Ethylene Oxide & Radiation Sterilization Workshop, Philadelphia. Contact: Nelson Laboratories, Salt Lake City, 801/963-2600.

October 9-12: TrackWise User Conference, San Juan, PR. Contact: Sparta Systems, 888/261-5948.

**October 10:** Regulatory Update: Antikickback, Web seminar. Contact: Regulatory Affairs Professionals Society, Rockville, MD, 301/770-2920.

October 12-14: ASTM International Committee E56 on Nanotechnology, Tampa, FL. Contact: ASTM International, West Conshohocken, PA, 610/832-9720.

**October 15–17:** Pack Expo, Las Vegas. Contact: Packaging Machinery Manufacturers Institute, Arlington, VA, 703/243-8555.

**October 23-24:** Good Monitoring Practices, Web seminar. Contact: Clinical Device Group Inc., Chicago, 773/489-5706.

#### November Highlights

November 5-7: European User Conference, Rome. Contact: Sparta Systems Europe Ltd., Ramat Gan, Israel, +972 3 7554040.

**November 11–15:** Photonics Asia 2007, Beijing. Contact: The International Society for Optical Engineering, 888/504-8171.

November 12–13: Principles & Practices of EU and U.S. Medical Devices, Brussels. Contact: Regulatory Affairs Professionals Society, Rockville, MD, 301/770-2920.

**November 13–14:** Clinical Trials Design, Web seminar. Contact: Clinical Device Group Inc., Chicago, 773/489-5706.

**November 14:** Nanotechnology, Web seminar. Contact: Regulatory Affairs Professionals Society, Rockville, MD, 301/770-2920.

November 14-16: ASTM International Committee D09 on Electrical and Electronic Insulating Materials, Tampa, FL. Contact: ASTM International, West Conshohocken, PA, 610/832-9728.

November 14-16: ComPaMED 2007, Dusseldorf, Germany. Contact: Messe Dusseldorf North America, Chicago, 312/781-5180. ■

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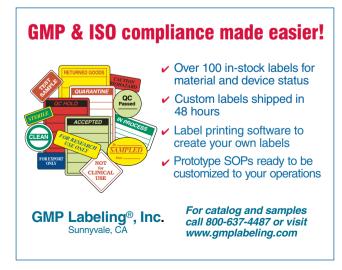


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## Fresenius Medical Care

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**Fresenius Medical Care** is the world's largest, integrated provider of products and services for individuals with chronic kidney failure, a condition that affects about 1,500,000 individuals worldwide. **FMC-North America Renal Therapies Group** has the following position available at its Ogden, Utah facility:

#### R&D Product Development Engineer II.

As a member of the product development team, this technical project leader will be key in the conceptualization, design, development and market release of innovative disposables for use in Hemodialysis and/or Peritoneal Dialysis.

Responsibilities: Full responsibility for major projects involving design and development of medical disposables. Integration of cGMP and FDA/ISO Design Controls throughout design and manufacturing transfer processes. Documentation of intellectual property including ideation, design and testing. Development of verification protocols, analysis of results and authorship of engineering reports. Awareness of new and emerging engineering materials, manufacturing processes and design tools. Support of product conceptualization and modeling.

Requirements: Minimum requirements include a BS degree in Engineering and minimum 3 years related experience (or MSME and 1 year





experience) in design and development, preferably with disposable medical products. Candidates must be knowledgeable with much of the following: design for manufacturability, design of injected molded components, polymer and elastomer application in medical products, assembly/joining methods, automation, materials testing, sterilization, statistics, cGMP, and FDA/ISO Design Controls. Solid analytical and technical writing skills are required.



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<b>Orchid Orthopedic Solutions LLC</b>	<b>Wabash MPI</b>
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## Diagnostic Powerhouse in the Making

Inverness Medical Innovations Inc. (Waltham, MA) is becoming the company to contend with in the diagnostics market. During the past year, it has aggressively engaged in several acquisitions in the United States and overseas to expand its product portfolio. Most notable is its recent success in outbidding Beckman Coulter Inc. (Fullerton, CA) for Biosite Inc. (San Diego) as part of its focus on becoming a leader in cardiac diagnostics.



Ron Zwanziger

This year has been especially busy for Inverness Medical. Less than a month after announcing its intention to purchase Biosite, the company acquired Cholestech Corp. (Hayward, CA), which further advanced its push to provide products that help diagnose and monitor cardiac conditions.

Inverness Medical was spun off from Inverness Medical Technology Inc. after it was sold to Johnson & Johnson in 2001. The remainder of the company that wasn't part of the diabetes market became what's known today as Inverness

Medical Innovations. The company's product categories are separated into consumer, professional, and cardiology diagnostics.

An initial focus on women's health in consumer diagnostics led to the launch of the company's flagship product, the Clearblue digital pregnancy test. The product put Inverness Medical on the rapid diagnostics map. The following year, the company expanded into professional diagnostics. According to Jon Russell, vice president of finance, Inverness Medical now offers close to 2000 products in professional diagnostics that test for more than 100 different disease states or targets. In just four years, this segment of the company grew from \$33 million to more than \$300 million, primarily through acquisitions.

Part of Inverness Medical's success can be attributed to its forward-looking approach in developing products. The company increased research and development spending from \$49 million in 2005 to \$70 million in 2006. In the past three to four years, cardiology diagnostics has been the focus of research and development efforts. At a healthcare conference earlier in the summer, Russell indicated that the company has a series of breakthrough cardiology products in its pipeline, especially in home and point-of-care diagnostics.

#### Focus Going Forward

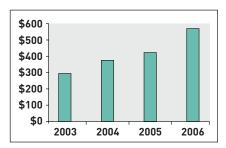
- Continue development of breakthrough cardiology diagnostic products.
- Prepare for mid-2008 launch of pointof-care congestive heart failure device for home use.
- Continue investment in R&D to push product development.
- Acquire point-of-care diagnostics provider HemoSense (San Jose).

"Inverness is committed to lowering total health costs, improving patient outcomes, and providing [products] for an empowered healthcare customer."

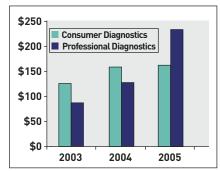
-Ron Zwanziger, CEO

COMPANY	PRODUCT/SERVICE
Biosite	Makes diagnostic tests for detecting blood clots, and for cardiovascular and cerebrovascular diseases.
Cholestech Corp.	Manufactures LDX system for testing lipids, glucose, and liver enzymes.
First Check Diagnostics LLC	Manufactures home testing kits for illicit drugs, cholesterol, and blood in stool.
Quality Assured Services Inc.	Provides home diagnostic tests.

Select acquisitions made by Inverness in FY 2007. The company also acquired several distribution companies for Canada, India, Belgium, and Italy.



Revenue growth (in millions) for Inverness Medical.



Product revenues (in millions), excluding royalty revenues.

#### Highlights

- June 2007: FDA clears marketing of BinaxNOW, the first U.S. rapid test for malaria.
- May 2007: Formation of SPD Swiss Precision Diagnostics GmbH with Procter & Gamble to develop home diagnostic tests.
- October 2006: Agreement with Chembio Diagnostics Inc. and StatSure Diagnostic Systems Inc. to market rapid HIV tests.
- February 2006: Acquisition of Acon Laboratories gives company its second manufacturing facility in China.

#### Leadership

Ron Zwanziger, chairman, CEO, and president David Scott, chief science officer

**Jerry McAleer,** vice president, research and development and cardiology

Hilde Eylenbosch, president, consumer diagnostics

David Toohey, president, professional diagnostics

**John Yonkin,** president, U.S. Point of Care, and president, Inverness Medical Nutritionals

Paul Hempel, senior vice president, leadership development and legal affairs David Teitel, CFO

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